Call for projects from February 13, 2023

Interdisciplinary research on the long-term effects of the SARS-CoV-2-pandemic

Disciplines: Basic, clinical and translational research, health services research, social sciences, child and adolescent psychiatry.

Submission date: 31.03.2023
Funding period: until 31.12.2025
Funding sum: 7.5 million Euros

COVID-19 FORSCHUNGSNETZWERK NIEDERSACHSEN

With **"long COVID[1]" and "post COVID[2]"** a new type of disease has emerged in the course of the SARS-CoV-2 pandemic, which poses enormous challenges to the German healthcare system. The prevalence varies greatly depending on the study, ranging from 1-2% to 10-20%. Considering the large number of COVID-19 cases, a high number of long/post COVID patients is to be expected, even assuming low prevalences. The clinical picture of long/post COVID is diffuse, the symptoms are manifold, diagnosis and treatment are correspondingly difficult. In order to be able to diagnose and treat patients effectively, medicine and life sciences are dependent on comprehensive findings on the causes and course of long/post COVID diseases from basic, clinical, and health services research.

At the same time, the societal and social impact of the pandemic is becoming increasingly evident in almost all areas of life and work, and psychological impacts are also on the rise. In order to develop strategies for coping with the consequences of the pandemic, a coordinated bundling of interdisciplinary and complementary expertise is necessary.

Funded by the Lower Saxony Ministry of Science and Culture, the COVID-19 Research Network of Lower Saxony (COFONI) was established in 2020 to address the acute course of the SARS-CoV-2 pandemic through a coordinated bundling of interdisciplinary and complementary biomedical expertise (https://www.umg.eu/cofoni/). Given the multiple long-term impacts of the SARS-CoV-2 pandemic on individual health and society as a whole, the COFONI research network is expanding to include clinical, health care, and social science expertise and will support relevant interdisciplinary research projects in Lower Saxony.

[1] Symptoms last for four to 12 weeks; [2] Symptoms last longer than 12 weeks and cannot be explained by other diagnoses

Subject of the project funding by COFONI

Funding is available for interdisciplinary, cross-site research projects in the following areas:

1. Basic and translational research on post COVID
2. Health services research with regard to the long-term impacts of the pandemic
3. Interdisciplinary research on pandemic long-term impacts on living and working conditions
4. Mental health of children and adolescents and their families

(For a detailed description, see Appendix 1 and https://www.umg.eu/en/cofoni/project-call/)

Special requirements for funding

In addition to the scientific originality and thematic fit of the applications, **cross-site cooperation of applicants from Lower Saxony** is a prerequisite and is mandatory for funding. **The combination of interdisciplinary and complementary expertise as well as a high translational potential** are essential decision criteria. In the field of social sciences, the cooperation with biomedical disciplines is desired explicitly, and must be integrated into the project concept, at least in perspective. Interprofessional cooperation between research and practice, for example cooperation with professional societies, associations, health insurance companies or care institutions, can be taken into account.

The research projects must meet high scientific standards, be internationally competitive, and will be reviewed through a quality-assured selection process. Due to the relatively short project duration, existing data/cohorts should be used. The linking of already collected data as well as innovative evaluation aspects should be in the foreground.

The **use of the central COFONI technology platform**, which provides overlapping data and biobanks as well as methods and animal models for shared use (see Appendix 2), is desirable in suitable project proposals and the use of comparable resources outside COFONI has to be justified. For the involvement of the technology platform, the respective contact persons of the technology platform need to be contacted in advance to plan the according budget and resources (see Appendix 2).

Grant recipients

Eligible for application are the universities of the state of Lower Saxony in accordance with § 2 of the Lower Saxony Higher Education Act (NHG) as well as non-university research institutions funded by the state. A forwarding to industrial partners is not possible. In exceptional cases, national and international research institutions as well as non-governmental institutions in municipal, non-profit or private sponsorship may also be involved. Eligible institutions may cooperate with non-university clinics and health care facilities funded by the state of Lower Saxony.

Project duration and budgets

Depending on the working hypothesis and the objectives, the duration can be flexible. The project start is planned for **July 1, 2023** with a maximum duration **until December 31, 2025**.

A maximum funding of **800,000 Euros** per project is planned. Depending on the objectives and relevance of the project, it is possible to apply for increased funding with appropriate justification. The work program as well as the required funding must be specified in detail. Therapy studies are only eligible for funding in the context of proof-of-concept studies with demonstrated feasibility within the specified project period.

Information on the funding procedure

The funding is restricted to the specific project purpose and is provided as fixed-amount funding in accordance with Sections 23 and 44 of the Lower Saxony Budget Code (LHO), including the associated administrative regulations (VV-LHO). The provisions of the General Auxiliary Provisions for Grants for Project Promotion (ANBest-P) and the LHO apply to the disbursement of funds. Further ancillary provisions are the COFONI publication regulations and, in the case of use of the COFONI technology platforms, the respective terms of use. Further information on the funding procedure can be found in Appendix 3.

Application

Detailed information on project funding and application are available on the homepage: https://www.umg.eu/en/cofoni/project-call/

Project applications must be submitted as a PDF file **by March 31, 2023 at the latest** to the following address: cofoni-lpc@med.uni-goettingen.de

Contact

Dr. Anika Appelles | Referent - COFONI Coordination Office https://www.umg.eu/cofoni/
Research focus "Long/post COVID, long-term effects of the pandemic"
Phone: +49 551 3961048 |e-mail: cofoni-lpc@med.uni-goettingen.de

Appendix

Research fields (**1**)

Technology platform (**2**)

Funding regulations “Hinweise zum Förderverfahren“ (**3**)

1. Investigating pandemic long-term effects in four research areas

1.1. Basic and translational research on post COVID

Severe fatigue with all its consequences for the quality of life of those affected is not a clinical picture that has recently emerged with the SARS-CoV-2 pandemic. Chronic fatigue syndromes are known as a consequence of many infectious diseases, e.g., EBV infections, but also as a consequence of autoimmune diseases. However, due to the high number of cases of COVID-19 disease, this condition has become a phenomenon with a substantial impact on health care.

Research into pathomechanisms

In spite of decades of research, there is still only rudimentary knowledge on the pathogenesis of chronic fatigue syndrome. There is no therapeutic option to date; up until now, not even randomized controlled pathophysiology-driven trials have been completed. Complicating matters further, fatigue is the most important symptom of post COVID disease, but not the only one. Exercise intolerance, memory, concentration and sleep disturbances, taste and olfactory disturbances, dyspnea, and various forms of cardiac arrhythmias also play a role. It is likely that different pathomechanisms underlie different symptomatologies, requiring different therapeutic approaches.

Better characterization of the disease and identification of targets for therapeutic approaches

Therefore, this project call aims to advance pathogenetic and immunological research on well-characterized patient cohorts in order to achieve a better characterization of post COVID disease on the one hand and to find targets for therapeutic approaches on the other. Therapeutic studies are eligible for funding within the scope of proof-of-concept studies with demonstrated feasibility in the specified project timeframe.

Preclinical model research with high translational potential

Experimental, preclinical model research for a better pathophysiological understanding of post COVID and with a high translational perspective are encouraged as well.

1.2. Health services research with regard to the long-term impacts of the pandemic

With long COVID and post COVID a new disease pattern has emerged in the course of the SARS-CoV-2 pandemic, which poses enormous challenges to the German health care system. The subject of health services research is the “last step" of the health care system, which means that it is characterized by its particular proximity to everyday patient care. In the context of long/post COVID research, the following research questions are to be systematically addressed - methodologically diverse and interdisciplinary connected:

Health care needs, health care situation and patient pathways

With regard to the care of patients with long/post COVID, it is necessary to go beyond epidemiological and biomedical studies and collect data on healthcare needs and preferences as well as the experiences of patients and their relatives or the family and social environment concerning the disease and the provided healthcare. Epidemiological studies can also contribute to describing the health care situation and deriving needs for action. In particular, the dissemination and use of evidence-based findings on the diagnosis and treatment of long/post COVID in everyday health care and the design of patient-oriented patient pathways across disciplines (e.g., general medicine, pediatrics, neurology, child and adolescent psychiatry, and youth welfare) and sectors (e.g., primary care, acute inpatient care, rehabilitation) are of great interest. In this context, questions of securing health care close to home, if necessary with the help of digital technologies, are also relevant.

Medical sociological and medical psychological aspects

Medical sociological and medical psychological aspects of long/post-COVID care are also largely unexplored. This includes studies on health inequalities according to socioeconomic status (housing situation, employment status, migration background) with regard to disease risks, disease severity, and chances of recovery as well as with regard to utilization behavior and access to care (access barriers, etc.). Furthermore, communication between physicians and patients is particularly challenging in the presence of large uncertainty regarding evidence-based diagnostic and treatment recommendations in long/post COVID. While the information needs of patients are maximally high, the competences and information situations on the part of the caregivers are often low at the same time. The associated challenges and communication strategies are largely unexplored.

Social acceptance and health literacy-sensitive communication

Additionally, a lack of acceptance of longer term and persistent courses of the disease is observed within the health care system, at the workplace, in educational and training institutions, as well as in the social environment. Moreover, as in comparable cases of chronic illness, there is a risk of stigmatization, especially in cases of diagnosed long/post COVID. Strategies and interventions of societal education are needed that use existing scientific knowledge of health and risk communication. In terms of health literacy-sensitive communication, communication strategies need to be aligned with target groups.

How healthcare facilities deal with the high demand for health care

Finally, it is also highly relevant to look at the professions within the health care system itself that are involved in providing health care. In principle, this applies to all the professions that work jointly in this field. Their work situation or work environment, but also their individual competencies and their professional understanding of the profession play a central role in providing high-quality healthcare to a large and growing number of long/post COVID patients. The best care infrastructure loses value if there is a lack of people who can use and develop it in a high-quality and professional manner. This situation also becomes more acute in quantitative terms when healthcare facilities have to deal with a shortage of staff in times of high demand for health care.

1.3. Interdisciplinary research on pandemic long-term impacts on living and working conditions

For the sociological assessment and analysis of the pandemic in general and for research on the social impacts of long/post COVID in particular, there is a lack of sociologically relevant and meaningful data sets on a local, national, and global scale. This is a significant deficit, and it is essential to collect relevant data with respect to work and life environments, to workplaces, and neighborhoods, to family relationships, and to generational relationships by using standardized or more open qualitative methods.

Therefore, a comprehensive strategy of data collection is needed in the context of long/post COVID research in order to be able to draw a larger, (socio-)medical as well as societal picture - both with a retrospective view on the course of the pandemic and with a view on the "societal future" (incl. estimation of follow-up costs) of long/post COVID. There is no doubt that, in addition to the medical aspect of the disease, social aspects also play a central role in the lives of affected individuals, in the everyday lives of their relatives, and also in the professional environment of their colleagues or employers.

Interdisciplinary research dimensions

The following research questions are to be addressed systematically, methodologically diverse, and connected in an interdisciplinary way:

- How conducive or obstructive are specific social contexts to chronification of long/post COVID or to its cure/mitigation? Where does illness begin and end, or where does health end and begin?
- What do the SARS-CoV-2 pandemic and long/post COVID imply for companies and employees in general? Which groups of employees and status groups, which sectors and branches of the economy have to struggle with long/post COVID in a particular way?
- Can the effects of COVID-19 or long/post COVID be more accurately described and typified to also be able to answer the question whether common patterns with other chronic conditions in the workforce can be identified?
- The question of transfer and communication (see also the remarks in 1.2 health services research) of scientific knowledge plays a central role. How can we, on the part of the scientific community, communicate long/post COVID, for example to employees, trade unions and employers, but also in social contexts of migration?

Challenges for the social sciences

In summary, this means for this field of research: the role of the social sciences is firstly to generate and process data extensively and in a quality-assured manner in order to shed light on as many aspects of the disease as possible on the basis of a solid database. Secondly, the social background of COVID-19 or long/post COVID must be systematically recorded in order to develop social and medical knowledge from the pandemic. Thirdly, significantly improved communication tools are needed. Preference should be given to projects that combine these three tasks. These may include projects that link to existing data sets, cohorts, and qualitative case studies. In this way, a complex long/post COVID understanding can emerge through collaborative interdisciplinary research. In this way, research projects aim to address health as a high social and public good in times of profound social transformations.

1.4. Mental health of children and adolescents and their families

Children and adolescents are one of the groups that have been, and continue to be, particularly affected by the global mental health impact of the SARS-CoV-2 pandemic, which is a cause for concern. Initial systematic reviews suggest a significant increase in suicide attempts, depressive disorders, eating disorders, and anxiety disorders in the age group up to 18 years (up to a 30% increase compared to pre-pandemic levels) as well as lack of learning progress during the lockdowns (loss of about 3 percentile points). In addition, some studies show that children and adolescents from households with lower levels of education are even more affected. In addition, many parents face unusual challenges and stress during the pandemic. High levels of parental stress may also adversely affect children's physical and mental health, as parents are not sufficiently available as regulators. The overall impact of the pandemic on children and adolescents may be long-lasting and may have long-term adverse effects on further social, cognitive, and psychological development.

Designing (preventive) intervention to improve mental health based on strong empirical evidence

In order to understand which factors negatively and positively influence children's mental health, learning behavior, and social skills during and after the pandemic, strong empirical evidence is needed.

Only then particularly vulnerable (or particularly resilient) subgroups can be identified and appropriate interventions (including preventive ones) can be designed to improve the mental health of children and adolescents in crisis situations. To date, most studies have focused on adults. The few studies on the mental health of children and adolescents, often do not take into account different developmental stages, data are usually collected only with the help of (online) questionnaires using (online) questionnaires and from only one source of information, usually an external medical history and the psychosocial circumstances of the family, the school situation, and information on previous illnesses are often not included.

Systematic approach to research questions

The following research questions need to be addressed systematically:

- **How has child and adolescent mental health evolved during the pandemic and what are important moderators and mediators?** Carefully designed studies with larger samples that include diverse, well-characterized subgroups and taking into account the course of the SARS-CoV-2 pandemic (pre-post, at multiple time points) are needed. Data collection via interviews and standardized surveys, health service utilization, and access to health care **as well as intra- and extra-familial psychosocial stress need to be investigated.**

- **How should the impact of the SARS-CoV-2 pandemic on the mental health of mothers and fathers on the longitudinal development (psychological, cognitive, social) of their children be assessed?** Developmental trajectories over multiple time points need to be considered. The intergenerational effects of the SARS-CoV-2 pandemic on physical and mental health need to be assessed**.**

- **How can we develop and implement effective surveillance and screening programs to identify children at risk early and strategically?**

- **How can we design relevant support programs including prevention/early intervention, telemedicine interventions to reach them at an early stage in order to strengthen the resources especially of socially disadvantaged children and their families and to help them to cope with their mental, social, and school-related problems?**

Central COFONI Technology Platform

The structural core in the COFONI research network is a **central technology platform** that provides overarching methods and animal models as well as databases and biobanks available with maximum efficiency for all participants to share. The following **parts of the technology platform** are presented individually below:

1. Animal models and test systems (contact persons),
2. Research biobanks (contact persons), and
3. Research database (contact persons).

For the involvement of the central technology platform, the respective local contact persons of the facilities must be contacted in advance. In consultation with the responsible persons, it must be clarified to what extent additional costs for the services have to be included in the project application. Extensive services of the technology platforms beyond consulting and provision of basic infrastructure (e.g., use of high performance/GPU clusters for data analyses, FAIR-compliant modeling, and tuning of new data models beyond the German Corona Consensus Dataset GECCO, or performance of project-specific animal experiments) have to be included in the budget planning of the projects upon consultation.

1. Animal models and test systems

For the interdisciplinary treatment of the SARS-CoV-2 research questions addressed in the various key areas, the **University of Veterinary Medicine Hannover, Foundation (TiHo)** provides all project partners within the network with state-of-the-art laboratories and animal housing for Biosafety Level 3 (BSL 3) experiments at the **Research Centre for Emerging Infections and Zoonoses (RIZ)** within the framework of cooperation projects. The extensive logistical equipment for BSL 3 animal husbandry and the great expertise and experience in dealing with corresponding pathogens such as SARS-CoV-2 make this TiHo facility a central partner in COFONI. The RIZ with its BSL 3 laboratories has a multi-level safety system including a thermal wastewater system and double HEPA filtration of individual laboratory tracts, which prevent the pathogens from escaping into the air. The technical systems and equipment were checked in a lengthy test phase, and workflows, maintenance, and emergency processes were intensively validated and trained. Since January 2020, the BSL 3 laboratory and also the Animal Biosafety Level 3 (ABSL 3) Facilities have started operations in handling human pathogenic aerosol transmissible pathogens. Extensive work in the BSL 3 laboratories at the RIZ is carried out by numerous renowned scientists under the coordination of Professor Maren von Köckritz-Blickwede as Head of Scientific Administration and Biosafety and Professor Albert Osterhaus as Scientific Director, a world-renowned expert in the field of coronavirus research especially regarding SARS-CoV-1 and MERS-CoV.

At the RIZ, various experimental animal models in ferrets, hamsters, and mice are also established in the BSL 3 laboratories and used for studies for testing vaccines and new antiviral strategies. The highest possible standards in terms of animal welfare and biosafety are required for performing these animal experiments. The scientists involved like Professor Asisa Volz, Professor Wolfgang Baumgärtner, Professor Maren von Köckritz-Blickwede, Professor Guus Rimmelzwaan, and

Professor Albert Osterhaus have the professional expertise and also the institutional requirements with state-of-the-art building technologies to meet these standards.

To support the questions addressed in the COFONI research network, the previously established SARS-CoV-2 animal models will be further optimised for project-specific conditions under the leadership of Professor Volz and Professor von Köckritz-Blickwede as head of the technology platform in order to complement research results generated in patients in the best possible way. This includes the additional development of SARS-CoV-2 animal models that reflect particular pathophysiological conditions in humans, such as (1) specific pre-existing disease/immunosuppression, and (2) age or even long/post COVID pathologies. These models will be established within the central infrastructure and made available to the partners in COFONI including expertise in SARS-CoV-2-specific animal testing. As a partner, TiHo can provide the logistics and performance of animal experiments under BSL 3 conditions, including pathological examinations by the Institute of Pathology under the direction of Professor Wolfgang Baumgärtner, to all partners in COFONI within the framework of cooperation projects, thus providing a platform for regional research. This allows a fast implementation of testing of active substances and vaccines. The analysis performed in such animal models will be essential for using the data generated in COFONI for establishing new diagnostic methods as well as for developing new therapeutics and vaccines in humans.

Another essential part of this cross-site central project "Animal Models" is located at **TWINCORE – Centre for Experimental and Clinical Infection Research** and represented by Professor Ulrich Kalinke. Even before the central COFONI technology platform was established, a technology platform in the field of genetically modified mice was already in place, which is jointly supported and professionally organised by the Hannover Medical School (MHH) and the Helmholtz Centre for Infection Research (HZI). Mouse models of SARS-CoV-2 infection developed at TWINCORE are of particular importance for COFONI. Previously produced transgenic mice expressing the human receptor of SARS-CoV-2, angiotensin converting enzyme 2 (ACE2), which is an important enzyme in blood pressure regulation, and the renin-angiotensin system (RAS) will be combined with a tamoxifen-inducible deletion of the type I interferon receptor (IFNAR) on type II pneumocytes of the lung (Sftpc-Cre^{ER}IFNAR$^{fl/fl}$). Thus, the infectivity with SARS-CoV-2 of type II pneumocytes, which are an important target cell of SARS-CoV-2 in the human lung, can be further increased in mice. In this way, quality-controlled transgenic mouse models of SARS-CoV-2 infection can be made available to the partners in COFONI for various questions.

Non-human primates (NHP) are genetically, immunologically, and physiologically more closely related to humans than rodents and ferrets and better represent certain aspects of COVID-19 disease than small animal models. Therefore, important hypotheses developed in cell culture and/or small animal models need to be tested in NHP models. In particular, the immune systems of NHP and humans show strong similarities. NHP are therefore particularly suited to elucidate which processes are important for the establishment of a protective immune response against SARS-CoV-2 and how these processes are disrupted by the virus. With the help of NHP models, key insights into SARS-CoV-2 spread in the host and pathogenesis as well as its inhibition by vaccines, drugs and antibodies could already be gained at the start of the pandemic.[1,2] Today, NHP models continue to be of great importance for the analysis of, among other things, candidate vaccines and recombinant neutralizing antibodies, and are used to study virus replication and pathology after the acute phase of infection.

The Infection Biology Unit at the **German Primate Center – Leibniz Institute for Primate Research**

(DPZ) is headed by Professor Stefan Pöhlmann and has made important contributions to the study of SARS-CoV-2 infection, including the discovery of ACE2 as a receptor for SARS-CoV-2 and TMPRSS2 as an activating protease.[3] Together with the Laboratory Animal Science Unit, headed by Professor Rabea Hinkel, and partners at the TiHo, in particular Professor Albert Osterhaus, the Department of Infection Biology has established the SARS-CoV-2 infection of rhesus monkeys. This model reproduces a mild course of SARS-CoV-2 very well[4] and has been successfully used to demonstrate, among other things, the antiviral effect of a recombinant neutralizing antibody. In parallel with the TiHo, models are being established to represent pre-existing diseases and immune deficiencies. In addition, methods based on vector technologies and DPZ-licensed virus like particle (VLP) technology[5] will be established that allow targeted modulation of host cell factor expression in the respiratory tract. This approach can significantly contribute to identifying cellular factors as targets for COVID-19 therapy. The corresponding animal models will be established within the infrastructure and made available to partners in the consortium as part of a collaboration. In this context, the DPZ will take over the planning and execution of the NHP work, including the virological and immunological analysis of the animals, and will advise and assist in the submission of project applications for animal experiments.

Prior to testing in animal models, the efficacy of small molecule compounds and biotherapeutics must be demonstrated in target-based and cellular assays. Likewise, sufficient pharmacokinetic properties must be proven. In particular, the identification of good low molecular lead structures requires the profiling of a large number of compounds. The **Helmholtz Centre for Infection Research (HZI)** is a specialised centre for infection-related assays under S2 and S3 conditions within the European infrastructure EU OPENSCREEN. The existing infrastructure and technology were expanded as part of the COFONI project to profile active substances against SARS-CoV-2 in a cellular assay cascade. A plaque-based secondary assay is used in addition to a high-throughput primary assay in 384 microtiter plate format. Several cell lines and viruses are available. The infrastructure will profile compounds from the COFONI network and from other national and international partners. If larger numbers of active substances are found, these will be filtered and prioritised in accordance with industry standards based on chemical and biological data. In addition, bioanalytical capacity will be provided to determine drug concentrations and pharmacokinetic parameters from the animal models described above via high sensitivity quadrupole mass spectrometry.

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[1] Baum *et al* (2020), Science, https://pubmed.ncbi.nlm.nih.gov/33037066
[2] Munster *et al* (2020), Nature, https://pubmed.ncbi.nlm.nih.gov/32396922
[3] Hoffmann *et al* (2020), Cell, https://pubmed.ncbi.nlm.nih.gov/32142651
[4] Rockx *et al* (2020), Science, https://pubmed.ncbi.nlm.nih.gov/32303590
[5] Hoffmann *et al* (2016), Mol Ther Nucleic Acids, https://pubmed.ncbi.nlm.nih.gov/27003757

2. Research biobanks

Biobanks are responsible for the collection, processing, storage, and release of biospecimens and thus form the basis of a large part of medical research. Decisive for future analyses is the quality and standardisation of the processes. Biobanks form the basis for different research projects within COFONI.

The **Hannover Unified Biobank (HUB)** is the central biobank of **Hannover Medical School (MHH)**. It was established in 2012 to provide an infrastructure for the standardised collection and storage of high-quality biospecimens and associated data. Over the years, the biobank has expanded and now supports many Germany-wide multicentre studies. Headed by Professor Thomas Illig, the HUB has developed into one of the largest state-of-the-art biobanks in Germany and today manages approximately 3.22 million diverse biospecimens for a range of diseases.

The **Central Biobank of the University Medical Centre Göttingen (UMG)** was founded in 2015 as a central service facility of the UMG to support medical research. Through close collaboration with the UMG Laboratory (Central Laboratory) and the Institutes of Pathology and Neuropathology, processes for the collection and processing of liquid and solid biospecimens and parallel data acquisition have been standardised. To enrich the biospecimens with clinical data from patients, the Central Biobank exchanges information closely with the Medical Data Integration Center. It supports national as well as international multicenter studies while providing a prospective collection of biospecimens and data that researchers can access.

Since 2017, the Central Biobank UMG and the HUB have been members of the German Biobank Alliance (GBA), a German biobank excellence network funded by the Federal Ministry of Education and Research. Today, more than 30 biobanks of university hospitals and an IT expert centre are members of the GBA. The members have established uniform quality standards and provide biospecimens for various national and international research projects. Since 2017, Professor Thomas Illig has been the deputy spokesperson of the GBA. Furthermore, he is one of five coordinators of the National Research Network of University Medicine (NUM) in the field of "Cohorts and Biobanking" (NAPKON). PD Dr. Sara Nußbeck is a member of the GBA Steering Committee and leads the GBA subproject Education and Training.

As part of the Network of University Medicine, the National Pandemic Cohort Network (NAPKON) was funded, which recruits patients for COVID-19 research at 36 sites across Germany and stores the collected biospecimens locally. Patients are enrolled in three cohort platforms, the high-resolution platform (HAP), the cross-sector platform (SÜP), or the population-based platform (POP), and followed longitudinally until three years after infection. NAPKON makes the collected data and biospecimens available to research projects through a use and access process. The various NAPKON infrastructure cores subsequently process approved applications and provide the required data and biospecimens. The HUB is part of the infrastructure and, as a biospecimen core, is responsible for requesting the requested biospecimens from the individual sites and sending the biospecimens collectively to the applicants. The UMG participates in the biospecimen collection of the SÜP for the Göttingen site with 118 patients included so far (5th place of the university sites recruiting for SÜP), and the HUB participates in the biospecimen collection for the Hannover site in the HAP. Professor Thomas Illig is one of the five principal investigators in NAPKON, spokesperson for the biospecimen core, and serves on the Steering Committee and Use & Access Committee.

The NAPKON cohort currently includes a total of 6,715 patients with over 500,000 biospecimens. A comprehensive data set will be collected on the collected biospecimens in accordance with the "German Corona Consensus" (GECCO) with clinical data, diagnostics, interventions, demographic data, treatments, imaging data, and, as needed, specific data sets (pediatrics, neurology, etc.). A total of 2,520 patients in the cohort were systematically characterized for baseline, acute course, and a three-month follow-up. Ongoing analyses of this characterization include genotyping with GSA chips, transcriptomics and epigenetic profiling with EPIC array, ATAC-seq and ChIP-seq, proteomics, metabolomics, and a cytokine panel as well as viral typing, serum PCR, and serological spike, nucleocapsid, and neutralizing antibody assays. Subsequently, 600 patients of the analyzed collective will be selected on the basis of a post-COVID syndrome score and their 12-month follow-up will also be molecularly characterized. The planned analyses include transcriptomics and epigenetic profiling with EPIC array, ATAC-seq and ChIP-seq, proteomics, metabolomics, and a cytokine panel. All generated results of these analyses can be submitted to the Use & Access procedure in NAPKON.

Through funding from the Lower Saxony Ministry of Science and Culture (MWK), a longitudinal COVID-19 cohort with broad clinical data and diverse biospecimens has additionally been established at the HUB since 2020 under the direction of Professor Thomas Illig. In addition, data and biosamples are included from the Göttingen site (PD Dr. Sara Nußbeck, Central Biobank UMG). Together, data and biosamples from more than 400 patients are thus available. The cohort at the Hannover site will be continued by existing study personnel depending on the number of infected patients and will be continuously enlarged.

The biospecimen collection with MWK funding currently comprises more than 30,000 samples in Hannover alone, and more than 10 % of these were already assigned for analysis to a large number of research groups. The molecular characterization of the cohort was partly performed by the institutes themselves as well as in the context of COFONI projects. (i) Genome sequencing was performed from 140 patients and transcriptome sequencing from 210 clinically relevant time points. The generated omics data were already published within the German COVID-19 OMICS Initiative (Decoi) as well as the Host Genetics Initiative (HGI), and currently three additional research groups are working on the analysis of the data. (ii) The epigenome of 227 clinically relevant time points was longitudinally characterized and will be analyzed integratively together with the genome and transcriptome data as well as the clinical data. (iii) Furthermore, structural variants in 60 patients were investigated by optical genome mapping and preliminary results were already published. (iv) Genomic variants were investigated and published in an international Genome Wide Association Study (GWAS). (v) The immune response of the cohort was characterized using cytokines and leukocyte populations from plasma samples, and (vi) the heterologous immunity of the cohort was examined using B and T cell populations using Peripheral Blood Mononuclear Cells (PBMCs) from 128 time points. (vii) The transcriptome of specific cell types was analyzed using single-cell sequencing. (viii) Other projects include studying circulating non-coding RNAs and analyzing the metabolome profiles of long-COVID patients compared to convalescent patients. The projects can draw on an extensive set of clinical data, which was additionally collected for all severe and moderately severe visits following the German Corona Consensus (GECCO) dataset and the WHO clinical progression scale as well as a detailed post-COVID dataset established by the Pneumology Department of the MHH. Remaining gaps in the characterization of the cohort, especially in the study of post-COVID visits, can continue to be filled within the research network COFONI. In this context, the analyses will be performed at the Hannover and Göttingen sites according to their

expertise. The data collection will be continuously expanded.

Thus, with the close ties of the biobanks in Göttingen and Hannover to the German Biobank Alliance (GBA), expertise in quality management and harmonization in accordance with national and international standards is provided. The two biobanks prepare the samples appropriately (e.g., extraction of DNA and RNA or preparation of cell cultures) and send the samples to scientists for characterisation. The molecular data can be stored in the HUB in a systematic manner in the BIMS (Biobank Information Management System). This is done in close coordination with the Department of Medical informatics and the computation centers of the participating institutions.

3. Research database

All research data collected and processed within the framework of projects funded by COFONI that are relevant for reuse are modeled and provided with metadata according to the common FAIR criteria (findable, accessible, interoperable, and reusable) for research data management in accordance with good scientific practice, so that they are available to all researchers in the COFONI research network. For this purpose, a database infrastructure that can be used jointly within COFONI was set up by the two university hospitals involved, **UMG and MHH**. Further expansion will take place on a demand-oriented basis and in close coordination with the "Zukunftslabor Gesundheit" of the Centre for Digital Innovations Lower Saxony (ZDIN). The models of the national GECCO data set are the basis for this. Information and data models that go beyond the GECCO data set will be jointly adapted.

Applicant researchers must seek advice in advance from the contact persons at the research database regarding the necessary data and analysis infrastructure and, if they have wishes and requirements that go beyond the basic infrastructure, they must include appropriate funding in their project applications. The close coordination with the research database ensures a harmonisation of data sets and enables widespread further use within the COFONI network. Existing data can be used for new application projects. The research database offers to create appropriate tools (digital questionnaires, apps) for standardized data collection from study participants. The expenses for this are to be budgeted for in the applications in coordination with the contact persons of the research database.

Wherever possible, existing standards are used to describe the data (metadata). In close coordination with the researchers, data models will be agreed upon, implemented, and maintained in accordance with the HiGHmed data governance model.[6] In this context, the researchers are responsible for providing the content and checking the technical aspects of new data models. In the further course of the project, query and filter tools will be developed and made available to researchers on the basis of the standardised data models, as will the export into common data formats for analyses and the import of results. For the execution of computationally intensive data analyses, existing high-performance computers will be used as needed, or existing systems will be upgraded, operated, and made available. In the spirit of good scientific practice, the FAIR criteria will also be applied to analyses and their execution environments. For this purpose, in addition to common version control systems with internal and public domains, virtualisation options will also be provided and managed via container technologies.

Research Data Platform

The COFONI Research Data Platform is a secure, extensible, and interoperable platform for providing COVID-19 research data.

With this platform, the COFONI network promotes the translational idea of the network by providing researchers with a tool for reuse of structured COVID-19 research datasets from funded projects. These include clinical data (e.g., laboratory values, medical history/therapy data, and findings) as well as non-identifiable personal and interview data, e.g., social status, occupational status, and biography.

The data are available in anonymized form and can be requested by researchers for subsequent use. A graphical user interface can be used to compile cohorts and identify the number of cases. Hereafter, the created cohorts can be linked to a data use application. The data use application is then reviewed by a Use & Access Committee and, once approved, the requested data can be exported directly via the user portal in common file formats (.csv/ .json).

[6] Wulff *et al* (2018), Stud Health Technol Inform, https://pubmed.ncbi.nlm.nih.gov/29726437

Contact persons

(in alphabetical order)

1. Animal models and test systems

Prof. Dr. Mark Brönstrup
Abteilungsleiter Chemische Biologie Helmholtz-Zentrum für
Infektionsforschung
Feodor-Lynen-Str. 7-9
30625 Hannover
Mark.Broenstrup@helmholtz-hzi.de

Prof. Dr. Ulrich Kalinke
Institut für Experimentelle Infektionsforschung
TWINCORE – Zentrum für Experimentelle und Klinische Infektionsforschung
Eine Gemeinschaftseinrichtung des Helmholtz-Zentrums für Infektionsforschung und der
Medizinischen Hochschule Hannover
Feodor-Lynen-Str. 7-9
30625 Hannover
Ulrich.Kalinke@twincore.de

Prof. Dr. Maren von Köckritz-Blickwede
Leitung wiss. Administration und Biosicherheit,
Research Center for Emerging Infections (RIZ)
Leitung AG Biochemie der Infektionen,
Institut für Biochemie
Stiftung Tierärztliche Hochschule Hannover
Bünteweg 17
30559 Hannover
Maren.von.Koeckritz-Blickwede@tihohannover.de

Prof. Dr. Asisa Volz
Institut für Virologie
Stiftung Tierärztliche Hochschule Hannover
Bünteweg 17
30559 Hannover
Asisa.Volz@tihohannover.de

Prof. Dr. Stefan Pöhlmann
Deutsches Primatenzentrum GmbH
Leibniz-Institut für Primatenforschung
Kellnerweg 4
37077 Göttingen
spoehlmann@dpz.eu

2. Research biobanks

Prof. Dr. Thomas Illig
Leiter der Hannover Unified Biobank
Medizinische Hochschule Hannover
Feodor-Lynen-Str. 15
30625 Hannover
Illig.Thomas@mh-hannover.de

Dr. Stefanie Mücke
Projektmanagerin „COFONI“ der Hannover Unified Biobank
Medizinische Hochschule Hannover
Feodor-Lynen-Str. 15
30625 Hannover
Muecke.Stefanie@mh-hannover.de

Dr. Sonja Volland
Projektmanagerin „COVID-19 Biobank“ der Hannover Unified Biobank
Medizinische Hochschule Hannover
Feodor-Lynen-Str. 15
30625 Hannover
Volland.Sonja@mh-hannover.de

PD Dr. Sara Nußbeck
Leitung Zentrale Biobank UMG
Universitätsmedizin Göttingen
Georg-August-Universität Göttingen
Zentrale Biobank UMG
Robert-Koch-Str. 40
37075 Göttingen
sara.nussbeck@med.uni-goettingen.de

Dr. Kristin Hummel
Projektmanagerin Zentrale Biobank UMG
Universitätsmedizin Göttingen
Georg-August-Universität Göttingen
Zentrale Biobank UMG
Robert-Koch-Str. 40
37075 Göttingen
kristin.hummel@med.uni-goettingen.de

3. Research database

Prof. Dr. Dagmar Krefting
Direktorin Institut für Medizinische Informatik
Universitätsmedizin Göttingen
Von-Siebold-Str. 3
37075 Göttingen
dagmar.krefting@med.uni-goettingen.de

Prof. Dr. Dr. Michael Marschollek
Leiter Peter L. Reichertz Institut für Medizinische Informatik
Medizinische Hochschule Hannover
Carl-Neuberg-Str. 1
30625 Hannover
Marschollek.Michael@mh-hannover.de

Hinweise zum Förderverfahren

„Interdisziplinäre Erforschung der Langzeitfolgen der SARS-CoV-2-Pandemie“

COVID-19
FORSCHUNGSNETZWERK
NIEDERSACHSEN

Version 1.0 / 13. Februar 2023

Inhalt

COVID-19-Forschungsnetzwerk Niedersachsen
https://www.umg.eu/cofoni/ | cofoni@med.uni-goettingen.de

Nachfolgende Hinweise sind bei der Planung und Einreichung der Projektanträge zu beachten.

I. Voraussetzungen für die Antragstellung

Neben der wissenschaftlichen Originalität und thematischen Passgenauigkeit der Anträge ist eine **standortübergreifende Kooperation niedersächsischer Antragsteller*innen Voraussetzung und verpflichtend für die Förderung.**

Die Verknüpfung interdisziplinärer und komplementärer Expertisen sowie ein hohes translationales Potenzial sind wesentliche Entscheidungskriterien. Im Bereich der Gesellschafts- und Sozialwissenschaften ist die Verknüpfung mit biomedizinischen Disziplinen als interdisziplinäre Kooperation ausdrücklich erwünscht, und muss zumindest perspektivisch in das Projektkonzept integriert werden. Interprofessionelle Kooperationen zwischen Wissenschaft und Praxis, beispielsweise die Zusammenarbeit mit Fachgesellschaften, Verbänden, Krankenkassen oder Versorgungseinrichtungen, können dabei berücksichtigt werden.

Die Forschungsprojekte müssen einem hohen wissenschaftlichen Anspruch genügen, international kompetitiv sein und werden durch ein qualitätsgesichertes Auswahlverfahren begutachtet. Aufgrund der relativ kurzen Laufzeit sollte auf bestehende Daten/Kohorten zurückgegriffen werden. Das Verknüpfen von bereits erhobenen Daten sowie innovative Auswertungsaspekte sollten im Vordergrund stehen.

Der Einbezug der zentralen COFONI-Technologieplattform, die übergreifende Daten- und Biobanken sowie Methoden und Tiermodelle zur gemeinsamen Nutzung zur Verfügung stellt (s. Anlage 2 Technologieplattformen), ist in geeigneten Projektvorhaben wünschenswert und die Nutzung vergleichbarer Ressourcen außerhalb von COFONI ist zu begründen. Für die Einbindung der Technologieplattformen sind die lokalen Ansprechpartner*innen für die **Budget- und Ressourcenplanung vorab** zu kontaktieren.

Die Antragstellenden sind verpflichtet, nationale und internationale Standards zur Qualitätssicherung der Forschung einzuhalten: Leitlinien der Guten Wissenschaftlichen[1] und Leitlinien zur Guten Epidemiologischen Praxis[2]. Zudem wird erwartet, dass die FAIR-Prinzipien (findable, accessible, interoperable and reusable) zum Datenmanagement Anwendung finden.

Bei Förderanträgen für klinische (Pilot-)Studien sind zusätzlich die folgenden internationalen Standards in der jeweils geltenden Fassung zugrunde zu legen: Deklaration von Helsinki, ICH-Leitlinie zur Guten Klinischen Praxis (ICH-GCP), EU-Richtlinie 2005/28/EG, EU-Verordnung Nr. 536/2014, CONSORT- und STARD-Statements.

II. Verwendung der Fördermittel (Finanz- und Kostenplan)

Antragsteller*innen können Fördermittel von bis zu 800.000 Euro pro Forschungsprojekt aus den COFONI-Flex-Funds beantragen (hierin sind ebenfalls die Kosten für die Nutzung der Technologieplattform enthalten, siehe I.). Je nach Zielsetzung und Relevanz des Vorhabens ist die Beantragung einer höheren Förderung mit entsprechender Begründung möglich. Die erforderlichen Fördermittel müssen im Vordruck **Finanzierungsplan** detailliert aufgeführt werden (s. Antragsformular 6.3 Finanzierungsplan).

[1]Vgl. Deutsche Forschungsgemeinschaft. (2019). Guidelines for Safeguarding Good Research Practice. Code of Conduct. http://doi.org/10.5281/zenodo.3923602

[2]Vgl. DGEpi. (2019). Good-Epidemiological-Practice-GEP-EurJ-Epidemiol. DOI: 10.1007/s10654-019-00500-x.

Zuwendungsfähig sind grundsätzlich alle zur Erreichung des Zuwendungszwecks erforderlichen und durch das Niedersächsische Ministerium für Wissenschaft und Kultur (MWK) im Rahmen der Zuwendungsgewährung anerkannten Ausgaben.

Hierzu zählen unter anderem:

- **wissenschaftliches Personal, ärztliches Personal, wissenschaftliche und studentische Hilfskräfte.**
  Als Grundlage für die Personalkosten dienen die aktuell gültigen Durchschnittssätze des Niedersächsischen Finanzministeriums.
  Ist bei Antragstellung bereits eine konkrete Person für die Bearbeitung des Forschungsvorhabens vorgesehen, ist dies im Antrag kenntlich zu machen. Die Personalausgaben sind in diesem Fall anhand der persönlichen Daten möglichst genau zu ermitteln.
- **Sach- und Reisemittel**, die ursächlich in der Durchführung des Vorhabens begründet sein müssen. Reisekosten sind nach den Vorschriften des Bundesreisekostengesetzes (BRK) in Verbindung mit den Vorschriften der Niedersächsischen Reisekostenverordnung (NRKVO) und den Verwaltungsvorschriften zur NRKVO (VV-NRKVO) vom 10.01.2017 in der derzeit gültigen Fassung förderfähig (Erläuterung: Förderfähig sind notwendige Ausgaben für Fahrten mit dem preislich günstigsten regelmäßig verkehrenden öffentlichen Verkehrsmittel).
- gegebenenfalls anfallende **Gebühren zur Nutzung von Sekundärdaten**.
- **Geräteinvestitionen**, die ursächlich in der Durchführung des Vorhabens begründet sein müssen und nicht zur Grundausstattung gehören können in begründeten Ausnahmefällen beantragt werden. Die Geräte müssen im Einzelnen genau bezeichnet und ihre Preise einschließlich aller Nebenkosten angegeben werden. Mindestens ein Angebot muss eingeholt und mit eingereicht werden. Des Weiteren finden die Regelungen des Niedersächsischen Tariftreue- und Vergabegesetzes Anwendung. Laufende Ausgaben für wissenschaftliche Geräte, z. B. für Energieverbrauch, Versicherungen, Wartung, Reparaturen und Ersatzteile, werden **nicht** gefördert. Es ist zu bestätigen, dass die sachgemäße Nutzung, Unterbringung und Wartung der Geräte sowie die Deckung der laufenden Ausgaben sichergestellt ist.
- **Druck- bzw. Publikationskosten** für die Veröffentlichung von Forschungsergebnissen (die Ergebnisse sollten möglichst in Open Access zur Verfügung gestellt werden).
- Fördermittel zur **Beteiligung von Patient*innen** (Aufwandsentschädigungen und Reisekosten).
- In begründeten Fällen können detailliert beschriebene Aufträge an Dritte beantragt und vergeben werden. Die beantragten Ausgaben müssen einen eindeutigen Projektbezug aufweisen; dieser muss ausführlich erläutert werden (s. **Angebotsvorlage für Unteraufträge**).

Zu den nicht-förderfähigen Ausgaben zählen:

- Ausgaben, die ursächlich der Grundausstattung des Antragsstellenden zuzurechnen sind
- die Erstattung von indirekten Kosten, d. h. Kosten für in Anspruch genommene Infrastruktur (z. B. Raum- oder Energiekosten)
- Ausgaben für Bewirtung und sonstige Repräsentationsaufwendungen
- Ausgaben für die Erstellung des Ethikvotums durch die hochschuleigene Ethikkommission sowie die Teilnahme an Inspektionen und/oder Audits.
- **Grundausstattung ist von den jeweiligen Zuwendungsempfängern bereit zu stellen.**
- Es kann **keine** Projektpauschale gewährt werden.

III. Hinweise zu den Zuwendungsbestimmungen

Zuwendungszweck

Zuwendungszweck ist die Förderung von interdisziplinären Forschungs- und Vernetzungsprojekten im Rahmen der „Interdisziplinäre Erforschung der Langzeitfolgen der SARS-CoV-2-Pandemie“.

Zuwendungszeitraum

Die Projektvorhaben können frühestens **ab Juli 2023 mit einer Laufzeit bis maximal 31.12.2025 gefördert werden.**

Zuwendungsgeber

Die Universitätsmedizin Göttingen (UMG) als Konsortialführung des COVID-19 Forschungsnetzwerkes Niedersachsen (COFONI) ist Erstempfänger der Fördermittel vom Zuwendungsgeber (Niedersächsisches Ministerium für Wissenschaft und Kultur) und kooperiert auf Grundlage eines privatrechtlichen Vertrages („Kooperationsvertrag“) mit den weiteren Gründungspartnern des Verbundprojekts COFONI (Deutsche Primatenzentrum – Leibniz-Institut für Primatenforschung, Helmholtz-Zentrum für Infektionsforschung, Medizinischer Hochschule Hannover und Stiftung Tierärztliche Hochschule Hannover).
Der Zuwendungsgeber hat die Weiterleitung von Mitteln der Zuwendung an die Verbundpartner zum Zwecke der Projektdurchführung gemäß Nr. 12 der Verwaltungsvorschrift (VV) zu § 44 Landeshaushaltsordnung (LHO) zugelassen.

Zuwendungsempfänger

Antragsberechtigt sind die Hochschulen des Landes Niedersachsen entsprechend § 2 Niedersächsisches Hochschulgesetz (NHG), sowie vom Land geförderte außeruniversitäre Forschungseinrichtungen. Eine Weiterleitung an industrielle Partner ist nicht vorgesehen.

In fachlich begründeten Ausnahmefällen können zusätzlich auch nationale oder internationale Forschungseinrichtungen – nicht jedoch mit einem Anteil von mehr als 15% der Fördersumme – sowie nichtstaatliche Partner in kommunaler, gemeinnütziger oder privater Trägerschaft hinzugezogen werden. In zwingenden Ausnahmefällen kann in Rücksprache mit dem MWK ein noch höherer Anteil für nicht-niedersächsische Partner zulässig sein. Antragsberechtigte Einrichtungen können mit durch das Land geförderten nicht-universitären Kliniken und Einrichtungen der Krankenversorgung kooperieren.

Rechtsgrundlage

Die Zuwendung ist zweckgebunden und erfolgt als Festbetragsfinanzierung gemäß der §§ 23, 44 der Niedersächsischen Landeshaushaltsordnung (LHO), einschließlich der dazu ergangenen Verwaltungsvorschriften (VV-LHO).

Sonstige Zuwendungsbestimmungen

Im Fall der Bewilligung an Zuwendungsempfänger werden die Allgemeinen Nebenbestimmungen für Zuwendungen zur Projektförderung (ANBest-P) gemäß § 36 Verwaltungsverfahrensgesetz (VwVfG) Bestandteil des Bewilligungsbescheides. Die Zuwendung darf nur insoweit und nicht eher angefordert werden, als sie innerhalb von zwei Monaten nach der Auszahlung für fällige Zahlungen benötigt wird (Nr.1.4 ANBest-P), anderenfalls sind nicht fristgerecht verwendete Mitteln zurückzuzahlen bzw. werden mit 5% über dem Basiszinssatz verzinst.

Von den Kooperationspartnern des Projektvorhabens ist ein*e Koordinator*in und somit eine koordinierende Institution zu bestimmen, die für die wissenschaftliche Federführung und i.d.R. für

die administrative Koordinierung, d.h. Weiterleitung und Bewirtschaftung der Fördermittel, verantwortlich ist.

Weitere Nebenbestimmungen sind in der jeweils gültigen Fassung die **COFONI-Publikationsordnung** und bei Nutzung der **COFONI-Technologieplattformen, die jeweiligen Nutzungsbestimmungen**. Aufgrund der besonderen Berichtspflichten des COVID-19 Forschungsnetzwerkes Niedersachsen gegenüber dem Niedersächsische Ministerium für Wissenschaft und Kultur ist im Sechsmonatsrhythmus ein kurzer Zwischenbericht und nach Abschluss ein kurzer Sachbericht (3-5 Seiten) vorzulegen, der über den Verlauf und die wesentlichen Ergebnisse des geförderten Vorhabens Auskunft gibt, d. h. zu Ausgangsfragen und Zielsetzung, Abweichungen vom ursprünglichen Konzept, erzielten Ergebnissen sowie aus dem Projekt hervorgegangenen Publikationen.

IV. Hinweise zum Antragsverfahren

Das Antragsverfahren ist einstufig angelegt.

Ab sofort und

bis zum 31. März 2023 (Eingangsdatum)

können Förderanträge in elektronischer Form der COFONI-Koordinierungsstelle vorgelegt werden:

Koordinierungsstelle COVID-19 Forschungsnetzwerk Niedersachsen (COFONI)
Dr. Anika Appelles | E-Mail cofoni-lpc@med.uni-goettingen.de
Universitätsmedizin Göttingen | Institut für Immunologie | Humboldtallee 34 | 37073 Göttingen
Telefon +49 (0) 551 / 39-61048 | Fax +49 (0) 551 / 39-5843

Dem Antrag ist für jede antragstellende Einrichtung das Formblatt „Erklärungen des Zuwendungsempfängers“ von dem jeweiligen Antragsteller/der jeweiligen Antragstellerin unterschrieben beizulegen. Für die Richtigkeit der Angaben wird empfohlen, die jeweils zuständige Drittmittelabteilung zurate zu ziehen.

Anträge, die nach dem oben angegebenen Zeitpunkt eingehen, können nicht berücksichtigt werden.

Die Einleitung des Prüfverfahrens unter Beteiligung externer Gutachtender erfolgt unmittelbar im April 2023. Die eingegangenen Förderanträge werden gemäß folgenden Kriterien bewertet und geprüft:

- Relevanz der Fragestellung im Sinne des Förderziels;
- interdisziplinäre und standortübergreifende Projektarchitektur;
- wissenschaftliche und methodische Qualität;
- Expertise des Projektteams;
- realistische Arbeits- und Zeitplanung;
- Angemessenheit der Finanzplanung.

Entsprechend der oben angegebenen Kriterien und Bewertung wird nach abschließender Antragsprüfung voraussichtlich im Mai 2023 über eine Förderung entschieden. Das Auswahlergebnis wird den Antragstellenden schriftlich mitgeteilt.

Der Projektstart ist für Juli 2023 geplant.