NFDI4Medicine

Binding letter of intent for proposal in 2019

1 Binding letter of intent as advance notification or non-binding letter of intent

X	Binding letter of intent (required as advance notification for proposals in 2019)
☐	Non-binding letter of intent (anticipated submission in 2020)
☐	Non-binding letter of intent (anticipated submission in 2021)

2 Formal details

- **Planned name of the consortium**

NFDI Consortium of the Medical Informatics Initiative (MII) and the German Centers for Health Research (DZG)

- **Acronym of the planned consortium**

NFDI4Medicine

- **Applicant institutions**

Applicant institution* TMF e. V. – Technology, Methods, and Infrastructure for Networked Medical Research, Charlottenstraße 42, D-10117 Berlin Chairman of the Board of Directors of TMF: Prof. Dr. Michael Krawczak, University Medical Center Schleswig-Holstein, Kiel	**Applicant institution*** DZD e.V. – Deutsches Zentrum für Diabetesforschung, Ingolstädter Landstraße 1, 85764 Neuherberg Chairman: Prof. Dr. Dr. h.c. mult. Martin Hrabě de Angelis
Spokesperson* Prof. Dr. Michael Krawczak, University Medical Center Schleswig-Holstein, Kiel, Chairman of the Board of Directors of TMF TMF on behalf of the National Steering Committee of MII	**Spokesperson*** Prof. Dr. Dr. h.c. mult. Martin Hrabě de Angelis, hrabe@helmholtz-muenchen.de, Institute of Experimental Genetics at the Helmholtz Zentrum München, Speaker and Member of the Board of the German Center for Diabetes Research (DZD) and current speaker of the DZG discussion forum
*** In the next months, the German Centers for Health Research (DZG) and the Medical Informatics Initiative (MII) will develop a common governance structure for this joint NFDI. Until such a structure has been defined, the Chairs of TMF and DZG are issuing this joint Letter of Intent.**	

3 Objectives, work programme and research environment

- **Research area of the proposed consortium**

22 Medicine

- **Concise summary of the planned consortium's main objectives and task areas**

The principle aim of the NFDI4Medicine consortium is to establish a quality oriented research data management as an integral part of the research data cycle in the patient-oriented medical research domain. In pursuing this aim the consortium will promote the FAIR principles (Findable, Accessible, Interoperable, Reusable) and the development of subject-specific and interdisciplinary services, standards and interfaces.

Objectives of the NFDI4Medicine consortium:

- Promote the definition and overall use of overarching **metadata standards** and ontologies to make the variety of medical data sets from patient-oriented medical research and health care as well as social data according to § 75 SGB X findable (F) and accessible (A) via an overarching metadata repository and provide a powerful search tool for scientists in medical research
- Strengthen the **interoperability** (I) across domains of comparable and prospectively combinable data sets by promoting the use of open, international standards for all levels of interoperability, thereby cooperating with **standardization bodies** and coordination with other NFDI consortia regarding the necessity of overarching legislative guidelines for standards (I)
- Promote uniform conditions for the **archiving of medical research data**, which vary according to the legal basis, e.g. on duration from 10 to 30 years (R) and for making patient-oriented medical data accessible within the legal framework
- Promote a **data sharing culture** to make data resources reusable (R) and to permit new and innovative research
- Adherence to **data protection laws** and regulations and to the **ethical principles** of medical research involving human subjects in combination with the further development of data protection guidelines to promote medical research
- To promote the **FAIR principles** in the whole research data management process which includes operational, technical, juridical and regulatory demands, e.g. see points above. Development of services and infrastructures for research data management, firstly for the medical domain and secondly across other domains.
- Address the need of specialists in many areas of computer science, in particular medical informatics, i.e **training and further education** of e.g. "data scientists"
- In general: Promote an interoperable research data management among the different institutes and organisations of the German scientific system

NFDI4Medicine will continuously use results from both, the DZG and the Medical Informatics Initiative, to contribute to the NFDI thereby **ensuring that there is no duplication of effort in NFDI and MII and the DZG, respectively,** and that no parallel infrastructures, standards or organizational structures are built up.

Task areas of the NFDI4Medicine consortium:

1. "Findable" (1st FAIR criterion)/inventory/search: Establishment of an inventory of data in (bio)medical research areas, accompanied by a) creation of structures and processes for metadata sharing (e.g. metadata registries, visualization of metadata), b) repository of methods and instruments for data collection (relevant for data provenance, data quality), c) search service for finding distributed, potentially available instance data.
2. "Accessible" (2nd FAIR criterion)/request brokerage: Establishment of an overarching request brokerage for access to databases ("instance data"), which is based on items from a previously mentioned search service (task 1c). This process bundles and expands existing tools and services.
3. "Accessible" (2nd FAIR criterion)/record linkage: Development of technologies and services for record/data linkage in order to be able to link heterogeneous personalized data across institutions and networks in an error-resistant manner under strict data protection and data security conditions.
4. "Interoperable" (3rd FAIR criterion)/distributed computing: Harmonization and further development of interfaces for distributed computing in the medical domain (relevant for a) data protection restrictions, b) large scale data to be shared/difficult to transmit)
5. "Reusable" (4th FAIR criterion)/metadata: Networking of (meta-)data across diseases using additional metadata. Augmentation and visualization of data with data from public databases (metadata catalogs, publication data "public knowledge", internationally used unique identifiers)
6. "Reusable" (4th FAIR criterion)/data protection and security: Establishment of (re-)consenting services in order to make data "reusable" in compliance with data protection requirements (e.g. further development and automation of templates, technical support for machine-readable declarations of consent, development of consulting services, cross-institutional and cross-network use of consents (e.g. using the record linkage developed in task 3).
7. "Reusable" (4th FAIR criterion)/data publication, archiving: Establishment of structures and processes for the facilitation of data publications in the (bio)medical domain, possibly also the transfer of valuable databases ("legacy data") whose data curation has expired as well as the annotation of clinical databases with regard to the use for machine learning procedures.

8. Clinical research data: Integration of healthcare data with clinical research data (study and cohort data) at the medical faculties and DZG sites in Germany towards a research data infrastructure, in close collaboration with other consortia in the medical sciences.
9. Basic research data: Processing and development of data types relevant for basic research in medicine and translational research, e.g. animal experimental, cell culture, organoid, omics data, etc. in a later stage of the consortium roadmap and in close collaboration with other consortia in the life sciences on these topics.

Core writing team (in alphabetical order, will take responsibility for selected tasks): Prof. Dr. Ganslandt, Prof. Dr. Hrabě de Angelis, Dr. Illigens, Dr. Jarasch, Dr. Lablans, Dr. Pollex-Krüger, Semler, Dr. Wissing. Further experts from DZG and MII will be included.

- **Brief description of the proposed use of existing infrastructures, tools and services that are essential in order to fulfil the planned consortium's objectives**

The consortium NFDI4Medicine is based on the technical and organizational infrastructures which have been established for the last decade in the German Centers for Health Research (DZG) and also within the Medical Informatics Initiative (MII) since 2016. MII is completely funded by the BMBF, while DZG are funded by the BMBF and the federal states (Bundesländer). The planned joint research data infrastructure will consist of German university hospitals (data integration centers), university departments, non-university departments (Societies of Helmholtz, Leibniz, Fraunhofer and Max-Planck) and other institutions. Together, DZG and MII comprise close to a hundred research institutions and university medical sites across Germany. VUD[1], MFT[2], and TMF[3] represent the MII coordination office and bring in their unique networks of medical university hospitals, the German medical faculties and medical research projects and networks, respectively. DZG are organized in an overarching discussion forum and several working groups, e.g. for information technology.

The two existing research infrastructures in the medical domain - DZG und MII - aim at multi-site data sharing and knowledge exchange between different institutions and the combination of health care, clinical and biomedical translational research which anticipate many of the main goals of the NFDI. The consortium NFDI4Medicine therefore will build on the developments of the MII and the DZG and will bring in continuously their results into the NFDI.

[1] Verband der Universitätsklinika Deutschland e.V., www.uniklinika.de
[2] Medizinischer Fakultätentag, medizinische-fakultaeten.de
[3] TMF e.V., www.tmf-ev.de/EnglishSite/AboutUs

- **Interfaces to other proposed NFDI consortia: brief description of existing agreements for collaboration and/or plans for future collaboration**

Depending on the submission or success of the applications of other consortia, the following agreements exist or are planned in future.

Existing agreements:

- NFDI4Health and GHGA - The GHGA, NFDI4Health and NFDI4Medicine consortia have agreed on a close partnership with one another. Together, these consortia provide perfectly complementary infrastructure components: bridging storage and management of medical research data (NFDI4Health), healthcare and patient-oriented medical research data (NFDI4Medicine), and omics raw data (GHGA). In this context, GHGA will provide large-volume data storage for omics raw data and expertise in the processing of this data. GHGA will work with NFDI4Medicine on standardization of data exchange formats. Ethical, legal, and societal impacts are synergistic cross-sectional topics for all three consortia.
- NFDI4Ing – cooperation agreement: The interface between medical and engineering sciences is rapidly gaining momentum on both sides. Common research topics as micro technology, medical device technology, simulation assisted surgery or ergonomics require an intensive exchange of patients and test persons´ data which needs to be addressed. Besides common data standards, the data privacy aspects are a central aspect of the common usage of personal data at this interface between NFDI4Medicine and NFDI4Ing.
- NFDI4Crime - Agreement to collaborate on overarching topics, e.g. use of MII medical Core Data Set in NFDI4Crime, data sharing and privacy concepts as well as terminology services.
- ForumX – Plan to work together in the area of methodical data processing, metadata standards, metadata mapping and harmonization, workflow standards, Snomed CT, handling sensitive personal data from participants and patients in lab experiments and clinical studies.
- MDM: MDM (Portal of Medical Data Models) and NFDI4Medicine are planning to discuss and to evaluate possible contributions of MDM to the task area 1 inventory/search (see above) as well as enrichment of medical metadata/semantic annotation.

Plans for future collaboration:

Future collaborations are planned with NFDI-Neuro, 4NFDIBiobanks, NFDI4Life Umbrella, MPOG-G, DIPOM, KonsortSWD, NFDI4Agri, and with other successful consortia.

Furthermore there will be a direct connection and cooperation through MII with DESAM-ForNet, the first nationwide research network in the out-patient sector, starting early in 2020, executed by DEGAM (German College of General Practitioners and Family Physicians) and TMF. The cooperation between MII and DESAM-FortNet will allow to bridge the gap between research infrastructures of the clinical in-patient sector and the ambulant GP-based out-patient sector.

4 Cross-cutting topics

- **Please identify cross-cutting topics that are relevant for your consortium and that need to be designed and developed by several or all NFDI consortia**

- Interoperability/standardization of data/metadata on the basis of international standards
- Data protection, ethics and data security
- Data Quality
- Data Sharing

- **Please indicate which of these cross-cutting topics your consortium could contribute to and how**

- Interoperability: MII Joint Interoperability Key Issues Paper and further agreements on standardization among the German university hospitals and medical faculties. DZG have developed disease-specific datasets forming, inter alia, the basis for the consortium-overarching dataset required by MII. In oncology, a cooperation between DKTK/Cancer Centers and MII is already initiated.
- Ethics: DZG have been collecting patient-related data for a decade and created the required patient consent templates and have established awareness and a working mode with ethics committees and data protection officers. Going even further, a broad consent has been coordinated by MII with the data protection supervisory authorities and the national ethics committee in Germany for the first time. The broad consent form and additional documents will be open for general use after conclusion of the pilot stage, currently undertaken in MII.
- Data protection: The DZG-developed “Mainzelliste” pseudonymization solution has been perpetuated in the DFG-funded “MAGIC” project and is now available for use in all NFDI consortia. TMF will bring in its decade long experience in developing generic data protection concepts and harmonizing them with the German national and federal data protection authorities as well as its experience on consultation service on data protection concepts.
- Data sharing: MII Uniform Use and Access Policy Key Issues Paper, existing data sharing processes in DZG