NFDI4Health

Letters of Intent
for Renewal Proposals in 2024

Please address the following aspects in your letter of intent

1 Binding letter of intent as advance notification of a full renewal proposal

x	Binding letter of intent (required as advance notification for renewal proposals in 2024)

2 Formal details

- Name of the consortium
  National Research Data Infrastructure for Personal Health Data
- Acronym of the consortium
  NFDI4Health
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- Prof. Dr. Henry Völzke, German National Cohort e.V. (esp. local study centres), Heidelberg (NAKO)
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3 Objectives, work programme and research environment in the second funding period

- Research area of the proposed consortium (according to the DFG classification system: www.dfg.de/dfg_profil/gremien/fachkollegien/faecher/index.jsp)
- 205-01 Epidemiology, Medical Biometry/Statistics
- 205-02 Public Health, Health Services Research, Social Medicine
- 205-07 Medical Informatics and Medical Bioinformatics
- 205 Clinical Trials (These refer to all medical subjects listed under review board 205.)

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

In accordance with the FAIR principles, NFDI4Health will create new opportunities for data analyses that will boost the scientific exploitation of personal health data and eventually improve population health. We will therefore follow our mission to increase the value of research in epidemiology, public health and clinical trial-based medicine by making high quality data internationally accessible. The overall goal of NFDI4Health is to support health researchers in sharing their data with the user community in a privacy preserving and ethical manner. For this purpose, we will consolidate and expand our data management procedures, services and standards to facilitate reuse of health data in close collaboration with our user communities, the Medical Informatics Initiative (MII), and the Network University Medicine (NUM). We pursue the following objectives: (1) to provide, consolidate and enhance the NFDI4Health framework for both centralised search and access to existing decentralised infrastructures for personal health data from clinical and epidemiological studies, public health surveys, disease registries, administrative health databases and health reporting in Germany; (2) to set up interfaces for health data exchange and harmonised data access jointly with MII and NUM to additionally link with, e.g., routine hospital data; (3) to facilitate creation of comprehensive datasets by enabling record linkage and federated analyses of personal health data; (4) to develop algorithms, services and software as well as tools for assessing data quality according to the FAIR for Research Software (FAIR4RS) principles and concepts; (5) to facilitate interoperable data sharing, e.g., by providing routines for data harmonisation and structures for federated data analyses and by promoting wide usage of common standards within the German landscape of research data infrastructures; (6) to further integrate our services and standards into the NFDI as well as into MII, NUM and other German and international initiatives such as the European Open Science Cloud (EOSC) and the European Health Data Space (EHDS) by taking advantage of the most recent national regulatory framework (e.g,. GDNG, DigiG).

In its second phase, NFDI4Health will consolidate the key elements of its infrastructure to (1) enhance functionality and content of the German Central Health Study Hub as central entry point for finding health data sources, (2) support the establishment of the German Portal for Medical

Research Data (FDPG)[1] in close collaboration with MII, NUM and federal agencies (e.g., the Health Data Hub (HDH) of the Federal Institute for Drugs and Medical Devices, Robert Koch Institute), and (3) expand the usability by further developing our services for the health research community and to public health services as well as by providing interfaces to other national research infrastructures.

Our work program consists of five task areas (TA). TA1 is devoted to the overall project management including budget planning, controlling and contract management as well as internal communication and reporting. Additionally, TA1 will continue to engage with policy makers, funders, research data infrastructures and other stakeholders to enable the long-term delivery of NFDI4Health services. The urgently needed business model will be developed to ensure sustainability of our services according to community needs and to enable data holding organisations to use our services. This will facilitate the reuse of health data in the long term.

Since close cooperation and exchange with other research infrastructures as well as strong involvement of the user community will play an even larger role in the second phase of NFDI4Health, TA2 will expand advisory, support and training services as part of our sustainability strategy to ensure a long-term cultural change in FAIR data sharing. We will thus equip our communities with skills to manage, share and use sensitive health data by establishing a help desk providing support regarding legal, ethical and technical aspects. In addition, we will provide an up-to-date NFDI4Health toolbox, that fulfils the FAIR4RS principles for facilitating reliable and interoperable management of health data. In addition, we will widen our scope by incorporating, e.g., medical societies and public health services in our activities. Eventually, to learn more about potential barriers in using our services, we will launch three research projects that build on the accessibility of personal health data and conduct thematic workshops as well as focus groups. TA3 will engage with the public to inform them about the benefits of health data sharing to improve population health and by this to increase their willingness to share their data. TA3 will also set up measures to facilitate networking with other NFDI consortia and within NFDI sections to ultimately support the establishment of one research data infrastructure in Germany. Moreover, networking with other national and international research data infrastructures, particularly in Europe, will be key to ensure the connectivity of German health research. TA4 is at the centre of our second phase. It will on the one hand consolidate our standards and services and on the other hand ensure their extension. As NFDI4Health´s major service, the German Central Health Study Hub will be further developed, with a focus on integrating other NFDI4Health and Base4NFDI services and on maturing its quality to ensure a secure and trustworthy operation. In close cooperation with other research infrastructures, we will build on the FDPG as access point to various data

[1] Originally developed by MII and extended by NFDI4Health in a close collaboration

sources in health research and establish a sustainable distributed data analysis infrastructure. Metadata standards for health data including interoperability and interface standards will be extended and harmonised across disciplines to serve the vision of one NFDI. This will also require setting up of routines for data harmonisation, which will be part of this task area. As already mentioned above, we will ensure the quality of our software and provide concepts and tools to also assess the quality of the data to be shared. TA5 will closely collaborate with other NFDI consortia and with existing (inter)national health research data infrastructures to implement use cases that cover the entire healthcare cycle from prevention to treatment and care and that will in particular deepen the measures of TA4.

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

NFDI4Health will on the one hand build on the infrastructures, tools and services that have been developed during the first phase of our project. These will be consolidated and expanded to cover the needs of wider user communities. As a core service, for instance, we will further develop our German Central Health Study Hub that offers a comprehensive overview of metadata from German clinical and epidemiological studies, public health surveys, disease registries, administrative health databases and health reporting. The metadata provided by the Health Study Hub comprise (a) metadata describing the covered health studies as such, health datasets and related resources such as study documents, and (b) metadata at the data element level, e.g., in the form of study-specific data catalogues. These metadata allow for a deep understanding of the datasets without making the data publicly available. On the other hand, as already done in the first phase, we will further exploit existing infrastructures. Here, e.g., the Health Study Hub will be closely linked to a multitude of existing local infrastructures including the Local Data Hub (LDH) solution, which is provided by NFDI4Health, or the emerging NUM study platform, which aims to support clinical multicentre studies. Additionally, the Health Study Hub will closely collaborate with the existing Portal of Medical Data Models regarding presentation, filtering, and comparison of variables. Summarising, the Health Study Hub will significantly facilitate the findability of German health resources and the publication of health data in an efficient and demand-oriented manner.

To support users with respect to the access of datasets, we will connect our Health Study Hub with the already existing FDPG, which will be further developed in close collaboration with the MII and other German research data infrastructures, ensuring a centralised and interoperable solution.

As a next step of the data sharing workflow, NFDI4Health will expand its services to harmonise data across studies, to assess their quality and to enable federated data analyses building on the existing DataSHIELD framework that allows the analysis of highly sensitive data. In this context,

we will explore the usage of a secure processing environment that will be provided by GHGA. This approach will be tested in a use case where datasets relevant for both consortia will be used. NFDI4Health will in addition draw on services that will be jointly elaborated with other consortia such as Base4NFDI, NUM and MII, as, e.g., the terminology service and metadata annotation workbench which are currently under development in the Base4NFDI TS4NFDI project.
Overall, since it is of the utmost importance to ensure interoperability with other German research data infrastructures, NFDI4Health is in close dialogue with relevant stakeholders to pave the way for the establishment of European Health Data Space.

Interfaces to other NFDI consortia

NFDI4Health pursues different ways for partnering with other NFDI consortia: (1) collaboration in sections, (2) participation in basic services or additional projects, and (3) direct collaborations.
(1) Sections: NFDI4Health co-applicants are actively involved in all NFDI sections. In particular, we chair the Section *Ethical, Legal and Social Aspects* (*ELSA*). Combining technical best practice and legal expertise, NFDI4Health contributes to harmonised data protection standards, security solutions, requests for interoperability and recommendations for legal compliance which are then made available to all consortia. As part of our activities in the Section *(Meta)data, Terminologies, Provenance*, NFDI4Health co-applicants co-founded the Working Group *Terminology Services* to promote common developments, share best practices, and reduce barriers to the use of terminologies. In the area of training and education, NFDI4Health interacts with various consortia at regional level and through the Section *Training and Education* (*EduTrain*). As member of its *Certificate Infrastructure Working Group*, we plan to build up a common modular educational framework for data literacy/stewardship by setting up a basic service from 2025 on. In collaboration with life science consortia and with *EduTrain,* local helpdesks or RDM services are empowered via train-the-trainer approaches to disseminate knowledge and concrete services at institutional level.
(2) Basic services/additional projects: As member of Base4NFDI, NFDI4Health is committed to develop basic services that will be provided to all consortia. As one important example, we actively contribute to the basic service *TS4NFDI* where a terminology service is currently being developed in close collaboration with NFDI4Chem and NFDI4Biodiversity. From June 2024 onwards, we will be working together with NFDI4Ing, NFDI4Chem, NFDI4Culture, NFDI4Memory, NFDI4BioDiversity and NFDI4Earth on setting up the basic service *DMP4NFDI* to support the widespread use of data management plans. Further, NFDI4Health co-applicants are committed to projects related to the *EduTrain* Section such as DALIA and FEdA and the successful graduate programme *Data Train*. *Data Train* was originally established by NFDI4Health in a joint initiative with NFDI4Biodiversity, KonsortSWD, NFDI4Earth and the U Bremen Research Alliance.

(3) Direct collaboration: NFDI4Health closely collaborates with GHGA, NFDI4Microbiota, NFDI4BioImage, NFDI4Immuno, and KonsortSWD to establish common metadata definitions and interoperability standards for the reuse of sensitive personal data. NFDI4Health also participates in the initiative of NFDI4BioDiversity and FAIRagro to network the helpdesks of the life science-oriented NFDI consortia, where we in addition closely work with FAIRagro on training, data quality assessment and on setting up central metadata-based search portals.
Finally, NFDI4Health represents the NFDI at high-level health-related events and in committees such as the German Health Infrastructure Coordination Group and coordinates NFDI responses to upcoming legislation, e.g., to integrate the NFDI infrastructures in the German and European Health Data Space.

4 International and national networking

To embed NFDI4Health activities in the (inter)national context, we have developed a three-pronged strategy: **(1) Community embedding:** With our active involvement in (inter)national infrastructures, projects, and standardisation initiatives, we aim to ensure compatibility and alignment of NFDI4Health endeavours with relevant (inter)national activities and to feed NFDI4Health requirements, e.g., in Standard Development Organisations (SDOs). HITS and BIH will continue to incorporate NFDI4Health requirements in ISO committees. The collaboration with the (inter) national Health Level 7 (HL7) community and SNOMED International will ensure the adoption of internationally agreed interoperability standards, especially HL7 Fast Healthcare Interoperability Resources (FHIR) and Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT) that will both serve as an important foundation for the EHDS. Close collaboration with relevant European projects such as xPanDH and xShare will ensure alignment with NFDI4Health. Several co-applicants are involved in working groups of the international Research Data Alliance. We also collaborate with the Maelstrom Research Group and with various partners in international projects to foster epidemiological study data harmonisation and standardisation. NFDI4Health provides tutorials and training workshops at (inter)national conferences and hand-on training in research data management and FAIR health data sharing as part of international training programmes as, e.g., in the project “Sharing and re-using clinical trial data to maximise impact” funded by the Doctoral Networks Programme of the Marie Sklodowska-Curie Actions. We also collaborate with the STRATOS initiative on guidance materials to better reach the biometric community. **(2) Technical embedding/linking of NFDI4Health services with (inter)national resources:** We will expand our ongoing activities to connect with other national and European health data platforms and resources. As described above, we collaborate with national infrastructures such as MII and NUM to ensure interoperability of our services on a national level and to align with the German node of the European Health Information Portal. This will enhance interop-

erability of NFDI4Health services on an international level and foster the use of international semantic and syntactic interoperability standards. Furthermore, we will consolidate alignments of the NFDI4Health metadata schema to other major metadata models, such as the Clinical Research Metadata Repository of the European Clinical Research Infrastructure Network (ECRIN), the EU clinical trials portal (CTIS), or the European Rare Disease Registry Infrastructure (ERDRI).
(3) Interacting with (inter)national infrastructures: Co-applicants will continue to be partners in European projects paving the road for a distributed infrastructure for health data, such as the European life sciences infrastructure ELIXIR. Regarding the federate analysis of sensitive health data, our co-applicants are members of both the DataSHIELD developer community and of the GO FAIR Personal Health Train Implementation Network. Most importantly, NFDI4Health will be at the forefront in implementing (meta-)data standards in Germany to ensure interoperability with the emerging EHDS for epidemiological, clinical and public health data.