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Information about the call (Part 1: Data custodians)

Grant capital:

DKK 50 million (total for both Part 1 and Part 2)

Award amount
Up to DKK 12 million per grant for data custodians

Application form opens: 14 May 2024, 12:00 pm CEST

Application deadline: 29 August 2024, 14:00 pm CEST

Applicant notification:

Part 1: October 2024 (eligibility)

Part 2: June 2025 (selection and grant)

Earliest start date: 1 September 2025

Latest start date: 28 February 2026

Review committees:

Part 1: Internal Novo Nordisk Foundation screening group
Part 2: Committee on Clinical and Translational Medicine (KTL)

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1 The NNF Sustain Programme

These guidelines are intended to assist you in the application process when applying for a grant from the Novo Nordisk Foundation (NNF). It is important that you carefully read these guidelines before initiating the application process.

The NNF Sustain Programme is an exploratory funding mechanism in a two-part process, as follows:

- Part 1: An Open Call for database custodians. As the NNF is exploring a new funding method, Part 1 of the Sustain Programme will be managed outside of NNF's grant management system, NORMA. Therefore, the database custodians should use this electronic form for their application. The purpose of Part 1 is to shortlist databases based on basic assessment of the FAIR principles and other eligibility criteria (see section 1.3 for further details). An internal NNF screening group will assess the applications based on these criteria. No funding will be granted in Part 1, but a budget is required of up to DKK 12 million (see section 1.5 for budget instructions). Once the assessment is finalised, all shortlisted database custodians will be notified and required to register in NORMA as peer reviewers. This is to ensure that database custodians are included in the process for validating research projects in Part 2.
- Part 2: An Open Call for <u>research projects</u> that make use of the databases shortlisted in Part 1. This call is managed in NORMA as other regular NNF Open Calls. Separate guidelines for Part 2 will follow at a later stage (Q4 2024). The external Committee on Clinical and Translational Medicine (KTL) will assess the research proposals. Based on this assessment, grants will be awarded to the researchers and to the database custodians that the researchers have selected for their projects.

NOTE: These guidelines apply to Part 1 of the NNF Sustain Programme.

The full application process is described in section 1.7.

Please note:

- If a shortlisted database is not selected by researchers, the database custodian will not receive funding.
- Database custodians, who are selected for funding in Part 2, are required to undertake additional steps including registering in NORMA and submitting a detailed budget.

NNF will treat all applicant and application information confidentially. Read more about how NNF processes personal data under 'privacy policy' https://novonordiskfonden.dk/en/privacy-policy/

Furthermore, please read 'General Terms and Conditions' for grants from NNF that all Grant Recipients must comply with: http://www.novonordiskfonden.dk/en/content/conditions-grants

1.1 PURPOSE

The purpose of the NNF Sustain Programme is to encourage the scientific use of existing data, specifically for cardiometabolic disease (CMD) research through a funding mechanism that supports both the custodians of the databases and the researchers who use the data The goal is to sustain high-quality health databases, encourage custodians to make data accessible, and ultimately advance understanding, prevention, and treatment of CMD.

1.2 AREAS OF SUPPORT

The NNF Sustain Programme aims to sustain existing databases and to support their custodians, when the data is accessible and used by researchers to advance understanding, prevention and treatment of CMD. Databases do not need to have a specific focus on CMD-specific indicators, but must contain data which may be used for research related to CMD.

In this context, we define databases as any datasets and the infrastructure around them which allows data collection, annotation, integration, cleaning, management, and efforts that promotes FAIR principles (outlined below in section 1.3) as well as secure and ethical use of data.

Database custodian applicants may apply for the operation, maintenance, extension, and/or improvement of existing datasets and infrastructures, but not to create new datasets.

Applicants can apply for support with hardware and skilled personnel who can offer training, consultation, data processing, data analysis, data management, software/database development, and dissemination of data/tools.

1.3 ELIGIBILITY AND THE 'FAIR PRINCIPLES'

Criteria to be shortlisted for the NNF Sustain Programme are as follows:

- The applicant (database custodian) must be employed at a university, hospital, or other non-profit research institution in Denmark. The applicant's hosting institution will receive and administer the grant.
- The data and infrastructure support applied for must be anchored at a university, hospital, or other non-profit research institution in Denmark.
- A hosting letter signed by the management at the institution must be included in the application.
 - o If the proposal requests funding for hardware, the relevant institution(s) must commit to hosting this in the hosting letter.
 - If the proposal requests funding to expand the data (e.g. by expanding the cohort, new analysis), the relevant institution(s) must commit to hosting this in the hosting letter.
- The database must contain data which may be used for research related to CMD, but does not need to have a specific focus on CMD-specific indicators.
- The database must adhere to specific requirements for the application of the FAIR principles. A questionnaire is provided in the online application form, so the applicant can self-assess. Briefly, the criteria are as follows (FAIR principles):

- The database must be *Findable*: the metadata is referenced on at least one public registry, with basic description of the dataset and contact details of the data custodian. Exclusion criteria include:
 - For Globally unique identifiers (Question 21):
 - No unique identifiers are assigned to datasets in the database, OR
 - Some datasets have non-persistent unique identifiers.
 - For Metadata identifier inclusion (Question 22):
 - Identifiers not included in metadata.
- The database must be *Accessible*: the data is hosted on a secured managed access system, and the process to apply for access must be publicly available. Exclusion criteria include:
 - For Metadata accessibility (Question 25):
 - Metadata not accessible if data is unavailable, OR
 - Metadata somewhat accessible, with limitations, OR
 - Metadata usually accessible, occasional issues.
- Level of *Interoperability*: the metadata states clearly whether the dataset can be linked with other data/registries. No exclusion criteria.
- The database is *Re-usable*: the metadata is available in English and states clearly the data type and provenance. Exclusion criteria include:
 - For Data provenance (Question 32):
 - No provenance information available, OR
 - Basic provenance information, limited details.

Applications must be complete and include:

- The required descriptive information about the database, custody, strategy, post-grant plan for sustainable access, description of ethical approval, GDPR, etc.
- A hosting letter signed by the management of the institution hosting the database.
- A written consent of the database co-custodian if any.
- Documents related to the ethical approval for the database.
- Budget (use the provided Excel template)
- If the strategy and budget include funding for hardware, include vendor quotes for the major equipment applied for.

Additionally, the following conditions are imposed:

- This grant cannot cover salary of the applicant, and the applicant must be guaranteed their own salary for the entire applied project period (3 years, 2025-2027).
- Applicants may submit only one application as a database custodian.
- Applicants who have submitted an application as a database custodian cannot submit an application as a researcher for a research proposal on their own database.

1.4 FUNDING

A total pool of up to DKK 50 million is available for grants awarded to data custodians and researchers. For data custodians, grants will be commensurate with the number of research

proposals submitted and selected for funding (up to DKK 12 million for one database if the maximum of three proposals are matched with that database). Data custodian applicants may not submit budgets below DKK 100,000.

Applicants may apply for funding for the following types of expenses:

- Operating expenses
- Equipment
- Infrastructure establishment and installation
- Salary for technical personnel
- Training of technical personnel
- Data management
- Administrative support

Administrative support may account for a maximum of 5% of the total budget and must be included therein. The administrative support:

- can cover expenses such as for accounting, payment of salaries, purchasing, hiring, as well as auditing and financial reporting on the project;
- cannot cover administrative expenses that are not directly related to the project; and
- is not automatically included in the grant and must be stated/applied for in the application budget, but should not be specified in detail.

NNF will not award funding for:

- Commercial activities
- Overhead
- Salary for the applicant

In relation to projects that are already partially or fully funded:

• If the database is partially or fully funded, the database custodian applicant must make this clear in the application form and account for it in the application budget form.

In relation to databases that have applied for other funding sources:

- If an identical or overlapping proposal has been submitted to other funding institutions than the NNF, it must be noted in the application.
- If the applicant, after submitting an application to NNF, receives funding for the database from other sources, the NNF must contacted immediately.

1.5 BUDGET

For creating a budget in Part 1, please refer to the list of eligible types of expenses above and use the template provided for download at the electronic form.

The applicant is required to submit a budget with up to three tabs, corresponding to the three funding scenarios:

- up to DKK 6 million, if matched with one selected research project.
- up to DKK 9 million, if matched with two selected research projects.
- Up to DKK 12 million, if matched with three selected research projects.

1.6 LANGUAGE

The application and any additional uploads must be written in English.

1.7 APPLICATION PROCESS

4 Database sucto Paris		
Call opens for database custodians.	14 May 2024	
Webinar for database custodians. Virtual event with	· · · · · · · · · · · · · · · · · · ·	
Q&A session for interested data custodians (not	28 May 2024	
Call closes for database custodians.	29 August 2024	
Notification of shortlisted databases.	October 2024	
Call opens for research applicants. Open call for		
_	Q4 2024	
	Q4 2024	
Call closes for research applicants.	Q1 2025	
Data custodians screen matched research proposals.		
The purpose of this step is for the database custodians	Q2 2025	
1 1 6 3		
Assessment of paired research proposals and databases		
by external committee.	Q2 2025	
The paired proposals will be assessed by the (external)	Q2 2023	
Committee on Clinical and Translational Medicine.		
Notification of granting (Part 1 and Part 2)	Q3 2025	
	Webinar for database custodians. Virtual event with Q&A session for interested data custodians (not mandatory). Call closes for database custodians. Notification of shortlisted databases. 2: Research applicants Call opens for research applicants. Open call for research projects utilising data from the shortlisted database. Webinar for researchers. Virtual event with Q&A session for interested researchers (not mandatory). Call closes for research applicants. Data custodians screen matched research proposals. The purpose of this step is for the database custodians to screen the research proposals for eligibility. Assessment of paired research proposals and databases by external committee. The paired proposals will be assessed by the (external) Committee on Clinical and Translational Medicine.	

1.8 ASSESSMENT CRITERIA



Applicants are encouraged to apply early and are welcome to consult us during the application process, so we can provide support in addressing specific concerns of their databases before the deadline.

Part 1: Database Custodians

The internal NNF screening group will assess the database applications based on the following criteria:

• The application meets essential eligibility criteria (highlighted in section 1.3 and the online form); and

• The application is complete and includes all relevant information and required attachments.

1.9 SUBMITTING THE APPLICATION

The application in its entirety must be submitted as follows:

- Use this electronic form: https://novonordiskfonden.dk/en/?page_id=613012
- Complete the budget using the <u>template</u> provided.
- Applicants will receive a confirmation as soon as possible.

Please note:

- All applicants must read and accept NNF's <u>Standards for Good Research Practice</u> before submitting the application. Further, the applicant must declare that the information provided in the application is true and accurate.
- An application cannot be submitted unless all the required fields have been completed.
 Applications can be cancelled at any time by the applicant before submission. If you need to withdraw an application after the deadline, please contact us via e-mail, using the contact information on page 3.

1.10 APPENDICES

- Budget (please use the provided Excel template)
- Hosting letter signed by the management of the institution (PDF)
- Written consent of the database co-custodian if any (PDF)
- Documents related to the ethical approval for the database (PDF)
- Vendor quotes (PDF)

The Novo Nordisk Foundation

The Novo Nordisk Foundation is an independent Danish Foundation with corporate interests. The objective of the Novo Nordisk Foundation is twofold: To provide a stable basis for the commercial and research activities conducted by the companies within the Novo Group and to support scientific and humanitarian purposes.

The vision of the Novo Nordisk Foundation is to contribute significantly to research and development that improves the lives of people and the sustainability of society.