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Benefiting people and society

INVESTIGATOR INITIATED CLINICAL TRIALS 2023

Information and guidelines for applicants

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Information about the call

Grant capital:
DKK 80 million

Award amount
From DKK 5 to 20 million per grant over a project period of 3-5 years

Application form opens:
May 12, 2023

Application deadline:
August 16, 2023 2pm (14:00 CEST)

Applicant notification:
Mid December 2023

Earliest start date:
January 1, 2024

IMPORTANT!
The grant cannot be activated until all approvals from the relevant public authorities have been obtained

Latest start date:
November 30, 2024

Review committee:
The Committee on Clinical and Translational Medicine

Contact:
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1 INVESTIGATOR INITIATED CLINICAL TRIALS 2023

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, as the guidelines contain the complete call text as well as instructions regarding the completion of the application.

NNF will treat all applicant and application information confidentially. Read more about how NNF processes personal data under 'privacy & security' in the online application system, NORMA. See how to access NORMA in section 2 of these guidelines.

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 is to strengthen the opportunities to carry out larger clinical trials in Denmark that **do not** have a direct industrial and/or commercial purpose. The ultimate objective is to improve the treatment of patients through new medicine and new technology and to ensure the highest quality in treatment.

Grants are available for both monocentric and multicenter national trials. If applying for a multicenter international clinical trial, the coordinating **investigator (main applicant) and the trial must be anchored in Denmark.** For international studies anchored outside Denmark, the grant can be applied for to cover only the part of the project carried out in Denmark, and in this case, it is important that the main applicant, who must be anchored in Denmark, has a key role in the clinical trials.

1.2 AREAS OF SUPPORT

Applications may be submitted for most types of larger clinical trials that include patients and aim to improve existing treatment routines (product development, analysis and follow-up are not considered a clinical trial). Randomized controlled trials are preferred; however, nonrandomized trials are also accepted. Examples include, but are not limited to:

- the use of medicines (including repositioning)
- medical technology (including testing medical devices)
- treatments such as surgical procedures, radiotherapy and new advanced genetic and cell therapy methods
  therapies such as physiotherapy or other intervention or rehabilitation initiatives

  The Programme supports investigator initiated clinical trials and projects aimed solely at discovery, product development or implementation **will not be considered**.

1.3 ELIGIBILITY

Clinical trials with an industrial and/or commercial purpose **will not be considered**!

Project:

- The clinical trials must conform to good clinical practice guidelines (GCP).
- Clinical relevance and scientific quality is imperative, and a detailed protocol including calculation of power, data management plan, and plan for statistical analysis of data must be included.
- All clinical trials that receive a grant from the Novo Nordisk Foundation **must be registered** at ClinicalTrials.gov or Clinical Trials Information System (CTIS).
- In case of industry sponsored material(s) there **must be a written agreement** (before project start) between the researcher and the industrial partner ensuring the researcher full ownership of obtained data and the rights to publish independently of the industry sponsor.
- When the clinical trial ends, the anonymized data **must be made available** to other researchers through public databases such as the Zenodo open data repository (CERN) or other equivalent databases.
- If an application for the clinical trial previously has been unsuccessfully applied for at the Novo Nordisk Foundation, it is imperative that it is described how the application has been improved since last submitting the proposal.
- An applicant can submit an application to the foundation before all legal approvals have been obtained, but the grant **cannot be activated** until all approvals from the relevant public authorities have been obtained. If a grant is not activated within one year following the date of the grant letter, the grant will be considered annulled.

Main applicant:

- The main applicant (investigator) must have a MD and must be a specialist physician or at a similar level. Main applicant must be employed at the hospital in Denmark where the project is anchored, and he/she **must be a clear driver/PI of the trial.**
- The main applicant must have documented experience in research leadership and well-documented research activities.
- The main applicant is responsible for the project and for scientific and financial reporting.
- Researchers who already hold an active grant within 'Investigator Initiated Clinical Trials' from the Novo Nordisk Foundation, as main applicant, are eligible to apply for a new grant during the final year of the existing grant. The grant period for the new grant cannot overlap the active grant. They can, however, be co-applicants on new projects/applications.

Sponsor:

- A sponsor is the institutional head of the department who assumes responsibility for initiating and leading a clinical trial (**cannot be the main applicant**).
- The institution at which the main applicant is anchored must take responsibility as a sponsor of the clinical trial. The sponsor has overall responsibility for the quality of the clinical trial and for ensuring that the clinical trial is conducted in accordance with Good Clinical Practice.
- The sponsor, together with the main applicant, must ensure that all the necessary permits are obtained and that all the relevant public authorities are notified.
- The sponsor must also take responsibility for administering the grant.

- A letter, signed by the institutional head, stating the role as sponsor for the trial, and administrative responsibility of the grant **must be uploaded** to the application (under 'uploads').

Co-applicant:

- The main applicant may have up to four named co-applicants. Co-applicants take an active part in organizing and implementing the project and will receive a share of the grant. The application must clearly describe the co-applicants' part in the project and their share of the budget.
- For each co-applicant, a short CV must be included in the application (one PDF file per co-applicant should be uploaded under 'co-applicants').
- Employees on the project (**including postdocs and PhD students) cannot be co-applicants.**

IMPORTANT RULES!

- An applicant may submit only one application to the Novo Nordisk Foundation for an "Investigator Initiated Clinical Trials grant". If an applicant submits more than one "Investigator Initiated Clinical Trials grant" application for simultaneously review, only the first application submitted will be evaluated, while the subsequent applications will receive administrative rejections.
- An applicant that holds an active "Investigator Initiated Clinical Trials grant" from the Novo Nordisk Foundation is only eligible to apply for a new "Investigator Initiated Clinical Trials grant" during the final year of the existing grant, and the two grant periods cannot overlap. I.e., recipients of NNF Investigator Grants 2018 will be eligible to apply in the 2023 Investigator calls and not before.
- While a project submitted to one call in the Novo Nordisk Foundation is under evaluation – a similar or overlapping project CANNOT be submitted to other calls from the Novo Nordisk Foundation. I.e., projects submitted for Distinguished Investigator grants cannot be submitted to any other calls in the Novo Nordisk Foundation until the outcome of this call has been publicised.
- It is permitted to hold two or more active grants of different types ('project', 'collaboration', 'challenge' and 'personal investigator'), i.e., researchers with an active grant of a specific type may apply for a new grant of a different type.

1.4 FUNDING

A total of up to DKK 80 million is available for grants between DKK 5 and DKK 20 for projects lasting up to 3-5 years.

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

- **Salary for a temporary employee** who will carry out the clinical responsibilities of the main applicant during the project period (up to 50%) – use **'substitute'** budget post.
- **Salary for technicians**, bio analysts, and other technical assistance, including laboratory administrators.
- **Salary for postdoctoral** researchers.

- **Salary for Ph.D. students** (including tuition fee up to DKK 80,000 per year, which must be specified/applied for separately in the budget).
- **Salary for research-year students**, up to DKK 150,000 per budget year.
- **Salary for employees or project consultants** at all staffing levels, including project management; however, researchers in permanent positions will not receive funding for their own salary.
- **Travel expenses** in relation to the project, e.g. conference and workshop participation and presentation of research results derived from the project.
- **Publication of results** originating from the project.
- **Communication** and outreach in the form of conferences, books, articles and other dissemination directly related to the project.
- **Equipment** required for the project, up to DKK 200,000 per budget year (can be combined in one of the budget years).
- **Operating expenses**: Direct expenses for developing, implementing and operating the project, including materials and equipment.
- **Consumables**, materials, animals, services, etc., directly related to the project.
- **Data management** collecting, organising, protecting, and storing data so it can be analysed.

Bench fee can be included in the budget for support of individual researchers to cover expenses needed to conduct the proposed research.

Bench fee is calculated per academic employee actively working on the project and may only be used for expenses that are related to the research project and which cannot be included within another individual budget category. Bench fee may account for maximum DKK 8.000 per month per FTE working on the project, and the budget must specify the expenses covered by the bench fee, which may include:

- Common or shared laboratory expenses and consumables
- Laboratory utilities (electricity, gas, water)
- Maintenance of essential equipment
- Service contracts
- Technical and IT support

Note, that bench fee cannot cover rent, administrative support, representation, social contributions etc. To include a bench fee in the budget, the fee must be a part of the general expense policy of the administrating institution, and it must apply for all employees independently of funding source.

Documentation that the administrating institution has a general bench fee policy should be included in the "Sponsor Letter" from the administrating institution or "Support Letter" from co-applicant(s) institution(s) enclosed as link or appendix. **An unspecified bench fee without documentation will not be accepted.**

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

- can via the host institution be shared between the institutions of the main- and co-applicant(s), as detailed in the application budget
- 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:

- the main applicant's or co-applicant's own salary
- commercial activities
- overhead
- Clinical trials with a direct industrial and/or commercial purpose
- Industry-initiated clinical trials, as well as drug testing derived from industry

The grant may not be used to cover 'overhead' (i.e. rent, electricity, water, maintenance etc.)

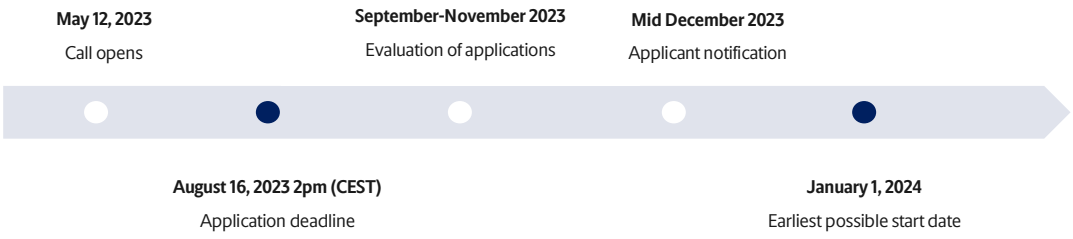
1.5 LANGUAGE

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

1.6 APPLICATION PROCESS

The application must be completed and submitted using NNF's online application and grant management system, NORMA, which can be accessed from: https://norma.novonordiskfonden.dk

Further information on how to access and navigate in NORMA can be found in chapter 2.



When all applications have been assessed, applicants will be notified about whether or not they have been awarded a grant. The notification e-mail will be sent from norma-noreply@novo.dk to the e-mail address entered on initial registration.

NNF does not provide feedback in case an application is not selected for funding.

1.7 ASSESSMENT CRITERIA

NNF's Committee on Clinical and Translational Medicine will primarily assess the applications based on the following criteria:

Quality, novelty, feasibility, clinical relevance of the project and the contributions and merits of the both the main- and the co-applicants.
If you have an active grant from NNF, this may be taken into consideration in the evaluation of your application for a new grant. In general, it is recommended that the Grant Recipient has delivered results on the active grant(s) before submission of a new application to NNF. If you apply, while having an active grant from NNF, you must describe how the project you propose in this application is different from and/or coherent with the project(s) already funded and briefly describe the progress of the already funded project(s).

2 THE APPLICATION AND GRANT MANAGEMENT SYSTEM – NORMA

Sections 2 and 3 provide guidance on completing and submitting an application through NNF's online application and grant management system NORMA. Section 2 contains general technical information, while section 3 contains information specific to the individual call. All the fields of the application form must be completed in accordance with these guidelines and the instructions in NORMA.

2.1 USER REGISTRATION

NORMA can be accessed through links on NNF's website or directly at:
https://norma.novonordiskfonden.dk

Before you begin, please read the instructions on the login page.

If you do not have a user profile in NORMA, you can register by clicking REGISTER from the login-page. Here you can also retrieve forgotten passwords by clicking the FORGOT PASSWORD-link. The main applicant should only have one user profile. Please use your work e-mail address for registration. After registration, you will receive an e-mail with your user name and a temporary password, which you can then use to log in to NORMA. After logging in for the first time you will be asked to provide a password of your own choosing.

A registered user who submits an application is legally responsible for the truthfulness of the content of the application.

If you experience technical problems, please contact NORMA Support: norma-support@novo.dk.

An applicant cannot change the e-mail address provided at registration.
Please contact NORMA Support if you need to change your e-mail address.

2.2 CREATING AN APPLICATION

Initiate an application by finding the call you wish to apply for in the OPEN CALLS-section on the Applicant Portal in NORMA. Use the search filters at the top of the section to filter by e.g., overall funding area, and initiate an application by clicking APPLY NOW next to the relevant call.

Applications can be edited up until the deadline. A draft application can be saved by clicking SAVE DRAFT and may be cancelled at any time up until the deadline by clicking CANCEL APPLICATION. An application is not submitted to NNF until an applicant has clicked SUBMIT and has received confirmation that the application has been successfully submitted.

You can review the application at any time by reopening from within NORMA. Opening the application will also allow you to download the application in its entirety as a PDF. Make sure the PDF is readable and formatted appropriately before submitting your application.

2.3 TEXT AND ILLUSTRATIONS

For all applications, the individual fields must be completed in accordance with these guidelines and the instructions supplied in NORMA.

To prevent loss of data, it is essential to press SAVE DRAFT before you leave NORMA or navigate in the system.

TEXT FIELDS
Text from Microsoft Word or comparable word processors can be copied and pasted into most text fields of the application. It is, however, important to check that formatting, special characters, and symbols have not been converted or lost in the text fields after copying and pasting. If the formatting looks wrong in NORMA or in the PDF, try changing all text to *Normal* using the FORMAT dropdown. It is the responsibility of the applicant to ensure that the pdf looks correct before submitting.

The available options for formatting text are at the top of the text fields. Some shorter text fields do not have the option to use rich text formatting.

For readability purposes, standard fonts, font size 11-12, and line spacing between 1.0 and 1.5 must be used.

ILLUSTRATIONS
Illustrations such as figures, charts, tables, images, etc. related to the project description can be uploaded under PROPOSAL. A Maximum of four illustrations are allowed. The illustrations will be placed on a separate page in the application PDF but can be referenced throughout the project

proposal as needed. For readability, please name the files numerically by the order in which they are referenced.

The following file formats for illustrations are accepted in the system: JPG, JPEG, PNG and BMP. The maximum accepted size for each illustration is 1050*1650 pixels.

2.4 SUBMITTING THE APPLICATION

The application in its entirety must be submitted electronically via the application system by clicking SUBMIT. It is not possible to submit an application or any part of it by standard mail or e-mail. Any material submitted outside the application system will not be included in the evaluation and will not be returned.

Please remember to check that the PDF version of the application is legible and contains all data and uploads before submitting.

All applicants must read and accept NNF's Standards for Good Research Practice 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 before submission. If you need to withdraw an application after the deadline, please get in touch with NNF via e-mail, using the contact information on page 3.

A list of any incorrect or incomplete entries will be generated at the top of the screen when you click SUBMIT. Clicking one of these error messages will take you to the relevant field. Amending incorrect or incomplete entries can be time-consuming, so we recommend submitting applications well before the deadline.

3 APPLICATION CONTENT

This section provides guidelines on the content required in the sections of the online application form for this call.

3.1 APPLICANT

The applicant tab contains various sections with information about the main applicant as well as any co-applicants:

- Administrating institution
- Applicant information
- Educational information
- Experience
- Co-applicant(s)
- Contact person
- Current institution
- Personal information
- Previous and Current Grants from NNF

The APPLICANT-tab contains information about all those involved with an application, meaning the main applicant or the contact person applying on behalf of an organization/institution as well as any co-applicants. Information about each applicant is collected through individual tasks in the APPLICANT DETAILS-section, detailing experience, publication history, application history with NNF, etc.

MAIN APPLICANT
The main responsible party for the application can enter their details through the Applicant Details-task with the type 'Applicant'. After filling in all mandatory fields, the applicant should complete the task to save the details.

It is only possible to be **main applicant on one application per application round.**

If a main applicant submits more than one application for this specific call, the first application submitted will be evaluated, while the subsequent applications will receive an administrative rejection.

As main applicant you **cannot apply** if you already hold an Investigator Initiated Clinical Trial grant, as main applicant.

PREVIOUS AND CURRENT GRANTS FROM NNF
If you have previously submitted other applications in the same calendar year, summarize how these applications are related to the current application.

If you have an active grant or have received any grants from NNF as an applicant or a co-applicant within the past five years, you must provide the application number, project title, grant period (in years), grant amount and the percentage share of the grant (100% if there is no co-applicant). Briefly summarize how any of the grants are related to the current application.

3.2 CO-APPLICANT(S)

It is possible to invite **up to four (4) co-applicants** in this call.

It is possible to be co-applicant on more than one application per application round. **However**, if a person is co-applicant on more than one application, the overall workload and commitment of the co-applicant may be taken into consideration in the evaluation of the application(s).

Co-applicants participate actively in organizing and implementing the project and receive a share of the grant. The project description should clearly describe the role of any co-applicants, and the budget should clearly indicate the co-applicants' share of the total budget. Co-applicants must be invited through NORMA and subsequently enter their details in the system. Please follow the instructions in NORMA on how to invite co-applicants to your application.

Note that inviting co-applicants can be time-consuming. Please start the invitation process as soon as possible and well in advance of the submission deadline

When the co-applicant accepts his or her invitation and has registered as a user in NORMA, they will gain access to the application. In addition, they will be assigned an APPLICANT DETAILS-task, available under MY TASKS from the APPLICANT PORTAL in NORMA. With this task, co-applicants should input details such as their institutional affiliation, work and publication history, application history with NNF and will be able to upload supporting documents such as a short CV (maximum two pages) or an endorsement from the institution.

Co-applicants will only be able to edit their own APPLICANT DETAILS-task, as well as make changes to the main application. The main applicant, on the other hand, can review and edit all Applicant Details-tasks for the application including those for co-applicants.

Please note that co-applicants can read, edit, and upload information in the entire application but cannot submit the application.

3.3 INSTITUTION

Please provide information about the institution where the grant will be administrated. This institution is where you will be employed during the grant period and the institution which will be responsible for budgeting, accounting, and staff supported by the grant.

Registering a new administrating institution in NORMA can take up two working days. The application can be edited but cannot be submitted before this information is registered. We therefore recommend that you register an administrating institution in good time.

3.4 PROPOSAL

Describe the project using the fields on the PROPOSAL tab. Each field (Project title, Brief project description, Project description, Illustration uploads, Lay project description, and Research methods) will have a short instruction text describing the expected input and maximum characters available.

PROJECT DESCRIPTION
Project description can be a maximum of 30,000 characters (including spaces, line breaks and special characters).

The project description should include:

- The purpose, procedure, patient selection and randomization.
- A brief review of the existing knowledge in the field, including a review of existing treatment methods and their effectiveness and side effects.
- A summary of the expected improvements that the clinical trial aims to achieve.
- A clear protocol and the calculation of statistical power.
- A data management plan.
- A plan for statistical analysis of the data.
- A plan for sharing the data with other researchers after the clinical trial ends.
- A report on the permits obtained from public authorities at the time of application.
- A list of abbreviations used in the project description.

It must be clear from the project description how the project collaboration is ensured, and the work is distributed between the main- and the co-applicants. The project can also be a clearly defined (and not yet funded) part of a larger, running project, but in this case, it must be clearly described in the application.

Abbreviations should be defined at the first use, and preferably a list of abbreviations should be included in the project description.

LITTERATURE REFERENCES
Please provide the reference information for the literature cited in the project description (maximum 4,000 characters, including spaces line breaks and special characters).

LAY PROJECT DESCRIPTION
Please provide a brief summary for non-experts in lay language. If the application is awarded a grant, the text may be used for publication (maximum 1,000 characters, including spaces, line breaks and special characters).

PUBLICATION LISTS
(for main applicant): can be a maximum of 5,000 characters (including spaces, line breaks and special characters). When providing the list of 10 publications for main applicant in the application scheme, please include the full author list, with own name **bolded**, and avoid the used of *et al*. Please consider making the main applicant's full list of publications available for the reviewers via ORCID.

CVs
Can be maximum 4,000 characters for the main applicant (including spaces, line breaks and special characters).

CV for co-applicant must be uploaded (see section 3.6). Please include in all the CVs a short bibliographic overview summarizing total number of peer-reviewed publications, number of first

authorships, number of corresponding authorships, number of citations and H-index. Please also include in the CVs an overview of current grants and indicate how much research time (in %) is committed to each of the projects.

Please note that the application should address all the assessment criteria listed in subsection 1.7.

3.5 BUDGET

The budget for the project applied for only comprises the information entered on the BUDGET tab. Additional budget information attached under UPLOADS or added on any other tabs than BUDGET will not be considered.

GRANT PERIOD

Before you can fill in the budget template, start by entering the start and end dates for the grant. This will determine the number of years available from the budget template. The grant period is the duration of NNF's grant for the project, and the budget counts years following the project start date rather than calendar years.

CREATE BUDGET

After saving the project start and end dates, the budget template will become available to edit. The budget will open in a new tab, in which you will need to add the subcategories you need for your budget. Please follow the instructions at the top of the screen to complete the budget.

Notes:

- The budget continuously saves changes you've made without the need to manually save. You are free to leave the budget at any time and come back at a later point.
- When you are done filling in your budget, please use the SAVE AND CLOSE button. This will check that all information has been filled out correctly and in accordance with the guidelines, saving the budget to your application.
- You can now return to the BUDGET tab. A summary of the budget will be displayed, review it to ensure that it is correct.
- The full budget details can be viewed or edited at any time before submission of the application by reopening the budget template.

Any comments about the budget can be entered in the SUPPLEMENTARY INFORMATION field.

Applicants may only apply for the types of expenses listed in subsection 1.4.

3.6 APPENDICES

Mandatory uploads:

1) CV for co-applicants (maximum of two (2) pages per co-applicant), must be filled out under 'co-applicants uploads' - **not under** 'other uploads'.
2) A signed letter from the institution taking responsibility for sponsoring the project and administrating the grant, must be uploaded under 'sponsor letters'.

Additional uploads:

If applying for bench fee, documentation that the administrating institution or co-applicant(s) institution(s) have a general bench fee policy must be uploaded under 'Other Uploads'.

All uploads must be in PDF format. NORMA automatically places these uploads at the end of the application. Please respect the page limitation and the upload requirements stated in the call. Uploads in excess of these limits may not be considered for evaluation.

Updated June 12, 2023

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.