INVESTIGATOR INITIATED CLINICAL TRIALS 2019

Information and guidelines for applicants
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Grant information

Grant capital:
From DKK 5 to 20 million per project over a project period of 3-5 years. Total grant capital in 2019 is DKK 80 million

Application form opens:
February 26, 2019

Application deadline:
June 13, 2019 2pm

Applicant notification:
Mid-December 2019

Earliest start date:
January 1, 2020

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

Latest start date:
November 30, 2020

Review committee:
Committee on Clinical and Translational Medicine

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1 INVESTIGATOR INITIATED CLINICAL TRIALS 2019

1.1 PURPOSE
The purpose is to strengthen the opportunities to carry out larger clinical trials in Denmark that do not have 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 key that the main-applicant, who must be anchored in Denmark, has a key role in the clinical trials.

1.2 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.
- The project must be anchored at a hospital in Denmark and must be led by a specialist physician.
- Any clinical trial that receives a grant from the Novo Nordisk Foundation must be registered at ClinicalTrials.gov or clinicaltrialsregister.eu (EudraCT).
- 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 be a specialist physician 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:
- 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 brief co-applicant statement and a short CV must be included in the application (combined into one PDF file per co-applicant and uploaded under ‘co-applicants’).
- Employees (including postdocs and PhD students) on the project cannot be co-applicants.

Collaboration partners:
- Collaboration partners are defined as researchers from Denmark or elsewhere who contribute scientifically to the project but who do not receive a financial share of the grant. If a specific collaboration partner is key to the project, a declaration signed by the collaboration partner should be uploaded under ‘Other Uploads’.

1.3 RESEARCH FIELDS
Applications may be submitted for most types of larger clinical trials that include patients and aim to improve existing treatment routines. 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

1.4 FUNDING
The budget frame for each grant is from DKK 5 million to DKK 20 million over a period of 3–5 years. The total grant capital in 2019 is DKK 80 million.

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1 A sponsor is defined in accordance with Sections 3–6 of Denmark’s Statutory Order on Good Clinical Practice.
Applicants may apply for:
- Salary for a temporary employee who will carry out the clinical responsibilities of the main applicant during the project period (up to 50%).
- Salaries for research assistants, associate professors, assistant professors, postdoctoral fellows, PhD students, nurses, secretaries, student assistants, consultants and statisticians.
- Operating expenses for: consumables, materials, services, data collection, data analysis, purchasing medicines and placebos, recruiting and following up on clinical trial participants, expenses for central randomization imaging, tests, monitoring, and other similar items directly related to the project.
- Project coordination: expenses directly related to implementing the project, obtaining the necessary permits, registering the trial, monitoring good clinical practice, internal coordination of the project, and networking activities relating to co-applicants and collaboration partners.
- Equipment required for carrying out the project.
- Data management: expenses for collecting, storing and statistically analysing the data.
- Conference participation: travel costs, accommodation, and registration at scientific conferences in Denmark and elsewhere that are directly relevant to the project.
- Publication costs: scientific articles, posters and other scientific dissemination activities based on the project.

The budget must describe any potential co-funding, and all aspects of the clinical trial must be fully transparent.

Applicants may not apply for:
- the main applicant’s or co-applicant’s own salary.

For administrative support of the grant, an amount up to 5% of, and included in, the funding applied for from the NNF may be included in the budget.

The administrative support:
- can cover non-scientific, administrative expenses in relation to the project, such as accounting, administration related to payment of salaries and 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-applicants, 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

The Novo Nordisk Foundation does not allow double funding of projects.
- If the applicant has received funding for the project or parts of the project from others, this must be included in the budget and there can be no budgetary overlaps.
- If an identical or overlapping project proposal has been submitted to other funding institutions than the Novo Nordisk Foundation, it must be noted in the application.
- If the applicant, post application submission, receives funding for the project or parts of the applied project from others, the Novo Nordisk Foundation must be contacted as soon as possible.
1.5 LANGUAGE
The application must be in English.

1.6 APPLICATION PROCESS
The application must be completed and submitted using the foundation’s electronic application and grant management system, "NORMA", which can be accessed from: [https://norma.novonordiskfonden.dk](https://norma.novonordiskfonden.dk). Further information on how to access and navigate in NORMA can be found in chapter 2.

It is important, that the applicant carefully reads these guidelines before initiating the application process, as this document contains the complete call text as well as instructions regarding the completion of the application.

1.7 SELECTION PROCESS
Applications are evaluated by the Committee on Clinical and Translational Medicine.

The committee will include in their assessment the quality, novelty, feasibility, clinical relevance of the project and the contributions and merits of the both the main- and the co-applicants.

1.8 IMPORTANT DATES

**February 26, 2019**
Application system opens

**Mid-December 2019**
Applicant notification

**June 13, 2019, 2pm**
Application deadline

**January 1, 2020**
Earliest possible start date
1.9 IMPORTANT INFORMATION WHEN COMPLETING THE APPLICATION

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 below). 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.

Publications list (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.

Supplementary Information (under the ‘Applicant information’ tab): Please describe the following terms of employment for both main- and co-applicants:
1) Affiliation with multiple institutions.
2) Time allocated to clinical work/research/teaching.

Project description: can be a maximum of 30,000 characters (including spaces, line breaks and special characters). The project description should include:
   o The purpose, procedure, patient selection and randomization.
   o A brief review of the existing knowledge in the field, including a review of existing treatment methods and their effectiveness and side effects.
   o A summary of the expected improvements that the clinical trial aims to achieve.
   o A clear protocol and the calculation of statistical power.
   o A data management plan.
   o A plan for statistical analysis of the data.
   o A plan for sharing the data with other researchers after the clinical trial ends.
   o A report on the permits obtained from public authorities at the time of application.
   o 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.

Illustrations: Up to four illustrations can be uploaded to the project description.

Layman project description: (in English) should be short and suitable for publishing on the Novo Nordisk Foundation website in case the project is funded.

Co-applicants: Declarations from all the co-applicants on their specific individual contribution to the project and a brief CV not exceeding two pages in total per co-applicant must be uploaded. It is important that section 2.4.4 is carefully read before inviting co-applicants in the system. If a co-applicant is already a user in the Novo Nordisk Foundation’s electronic application and grant management system “NORMA”, it is crucial that the invitation for the co-applicant is send to the email address, which the co-applicant has registered as his/her user email.
Mandatory uploads:
1) CV for co-applicants (maximum of 2 pages, pdf format per co-applicant), must be uploaded under ‘co-applicants’ - not under ‘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:
Collaboration statements from collaborators who are not co-applicants can be uploaded under ‘Other Uploads’.

If more documents are uploaded than the required, they will be deleted from the application before the application is send for assessment.
2 RULES FOR GRANT APPLICATION AND ACTIVATION

2.1 USER REGISTRATION
The Novo Nordisk Foundation (NNF) application and grant management system “NORMA” can be accessed through links on NNF’s website or directly at: https://norma.novonordiskfonden.dk

Before you begin, please read the instructions and technical information on the login-page.

It is possible to register as an organization in the application system, however organizations are currently only eligible to apply for open calls within ‘Social and Humanitarian Grants’ and ‘Education and Outreach Grants’.

If you hold an active grant, or if you have applied for funding from NNF recently, you may already exist in our system. You can check this by clicking “forgot password,” enter the email address you used when previously applying and request a new temporary password. If you are registered in our system, you will receive an email within 5-10 minutes with your login details and the temporary password. If you are not in our system, register as a new user.

The user registered, who submits the application(s) is ‘the applicant’, the legal entity responsible for the truthfulness of the content in the application.

If you experience problems logging in please contact NNF using the contact information on page 3.

2.2 GENERAL INSTRUCTIONS

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

IMPORTANT! To prevent loss of data, it is essential to press “Save Draft” before you leave NORMA or navigate in the system.

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

Submission
The application in its entirety must be submitted electronically via the application system. 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.

Applications cannot be modified after the submission deadline. If you wish to make changes to a submitted application before the submission deadline, it is possible for you (the applicant) to reopen the application. Be aware that the application must be resubmitted before the deadline in order to be evaluated.
Once the application has been submitted, a confirmation of receipt will be sent to the e-mail address used for logging into the system. If you do not receive a confirmation of receipt, you should contact NNF as soon as possible using the contact details on page 3.

Confidentiality
All applicant and application information will be treated confidentially.

2.3 IDENTIFYING THE CORRECT OPEN CALL IN NORMA

When you are logged into NORMA, you will enter ‘My Applications’, where you will find an overview of the status of your applications (in progress, submitted, approved and declined). In addition there is a ‘Pending Action’ section where there may be additional requests from NNF regarding your applications.

To initiate a new application you first need to identify the call and grant you wish to apply for. Go to the ‘OPEN CALLS’ tab, which is located in the upper right corner of the screen.

In the ‘OPEN CALLS’ window, all currently available grants from NNF are visible in seven tabs that are sorted by the foundation’s overall grant areas. Search the tabs to find the call that you wish to apply for.

2.4 CREATING AND COMPLETING AN APPLICATION

An application is initiated by clicking the blue “Apply Now” button, once you have identified the call and grant you wish to apply for.

Your draft application is then created and it will remain a draft version until you actively submit the application. After submission, you can continuously edit or cancel the application prior to the deadline. However, you are responsible for submitting or re-submitting before the deadline.

If you wish to withdraw a submitted application after the deadline you must contact NNF via email, using the contact information on page 3.
To submit the application, it is necessary to read and accept NNF’s standards for good research practice. A link can be found in the top right corner next to your name. Further, the applicant must declare that the information provided in the application is true and accurate.

You can at any time during the application process access a PDF view of your application, and you should always check to ensure that the PDF is readable and formatted appropriately before submission.

### 2.4.1 APPLICATION TEXTS

Formatted text from e.g. Word can be copied and pasted into most text fields of the application. It is, however, important to check that special formatting and special letters and symbols have not been converted or lost in the text fields after copying and pasting.

Available functions for formatting text are at the top of the text fields. Some shorter text fields do not have the option to format.

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

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### 2.4.2 ILLUSTRATIONS

In the ‘Project Information’ tab, figures/charts/tables/images, (etc.) related to the project description can be uploaded (maximum four illustrations is allowed). Include illustration number and legend/caption for each illustration file when uploading. The illustrations will be integrated in the final application PDF.

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

### 2.4.3 BUDGET

The budget template will be correctly generated once you have entered the Grant Period Start Date and Grant Period End Date, which can be found under the ‘Project Information’ tab, and pressed ‘Save Draft’. You must provide these dates, before entering any information in the budget. The budget must be entered in budget years following the grant period and not calendar years.

- To access the budget template press the blue ‘Open / Edit’ icon
- Press the ‘+’ icon to add budget rows
- For each budget row, choose a budget post from the drop down menu, specify details for the post under “Description”, and enter the amount under ‘Value’.
- All amounts must be stated in Danish Kroner (DKK) without decimals.
- When entering DKK amounts, do not use periods, commas or spaces.
- Save and close the template when the budget is completed.

Supplementary information for the budget requested from NNF can be entered in a separate field.
Funds applied or obtained from other sources must be entered under ‘Additional Contributions for the Project’. Please specify what the additional funding covers and state if there are any overlaps with the budget applied for from NNF.

2.4.4 CO-APPLICANTS
For certain calls, a number of co-applicants may be either required or allowed for the application. Co-applicants take an active part in organizing and implementing the project and will receive a share of the grant. The project description must clearly describe the co-applicants’ role in the project and the budget must clearly indicate the co-applicants’ share.

Co-applicants must be invited and accept their status as co-applicants in NORMA. To invite co-applicants, go to the ‘Invitations’ tab, which can be found on the left side of the screen. The main applicant must provide the full name, email and select role as ‘Co-applicant’ and then press the ‘Invite’ button. You will be notified by email once the co-applicants accept the invitation.

Co-applicants will be contacted by email from the main-applicant via NORMA and asked to confirm their status as co-applicants. The co-applicant has the option to accept or decline the invitation. If the co-applicant accepts, additional fields will be visible in the ‘Co-applicants’ tab in the application. The ‘Co-Applicant’ fields must be filled out by either the co-applicant or the main applicant. It is essential that the main applicant ultimately checks that the fields have been correctly populated before submitting the application.

A Short CV (maximum 2 pages) for each co-applicant must be uploaded to the application as a PDF file under the ‘Co-Applicants’ tab.

Co-applicants have the ability to read, edit and upload information in the entire application, however, cannot submit the application.

If co-applicants are mandatory, the application cannot be submitted before the required number of co-applicants have accepted. Please start the process of inviting co-applicants well in advance before submission deadline.

3 GENERAL RULES FOR GRANT APPLICATIONS

The general conditions (a-h) apply to grant applications to NNF

- The ‘applicant’ in the rules below refers to the main applicant responsible for submitting the application.
- There are no general rules for co-applicants.
- There may be additional application conditions for individual calls, if so these are specified in the guidelines in section 1 under ‘Eligibility’.
- If an applicant submits applications exceeding the allowed in points a-d, the latter application(s) will receive administrative rejection.
- Points g-h are relevant only if you currently hold an active NNF grant.

a) An applicant may submit only one application per call.

b) For the NNF grant type “Project grants”\(^{22}\), an applicant may submit only one application per calendar year.

c) An applicant may submit one application for either the NNF grant type “Investigator Grants”\(^{23}\) or “Postdoctoral fellowships” and may not submit another application for either grant type while the
application is under review. If the applicant receives a written rejection from NNF for the submitted application, the applicant may again apply for either grant type.

d) An applicant may submit only one application for a specific purpose/project per calendar year. Submitting two or more applications for different purposes/projects to different calls is permitted, as long as it is not to the same type of grant².

e) When applying for grants that do not allow funding for the applicant’s salary, the applicant must be able to account for own salary during the entire grant period applied for.

f) NNF does not allow double funding of project-specific expenses. If an applicant has applied for, or has received, funding for the project or parts of the project from others, this must be detailed in the budget of the application. If the applicant receives funding for the project or parts of the project from other sources following submission of the NNF application, NNF should be contacted as soon as possible.

g) It is not possible to hold more than one active grant of the same grant type². Researchers with an active grant of a specific type may be able to apply for a new grant of the same type during the final year of the grant, however, a new grant cannot be activated until the existing grant is completed and no longer active. The only exemption to this is that researchers with an active ‘Project Grant’²² awarded by a specific committee may apply for another ‘Project Grant’ while their current grant is active if all three following requirements are met:

• it is awarded by a different committee,
• it is for a different purpose/project, and
• the applications are not submitted within the same calendar year.

h) It is permitted to hold two or more active grants of different types², i.e., researchers with an active grant of a specific type may apply for a new grant of a different type.

² An ‘NNF grant type’ is defined by the general grant frame and/or support function. Three examples of individual NNF grants that are three different NNF grant types are: ‘Challenge Programme Grants’, ‘Steno Collaborative Grants’ and ‘Tandem Programme Grants’. Two examples of NNF grant types that include multiple NNF grants having the same general grant frame and support function are:

²² Type ‘Project Grants’ includes: Project Grants for Biotechnology-based Synthesis and Production Research; Project Grants in Endocrinology and Metabolism; Project Grants in Clinical and Translational Medicine; Project Grants for Clinical Nursing Research; Project Grants in Bioscience and Basic Biomedicine, Project Grants for Art History Research.

²⁹ Type ‘Investigator Grants’ includes: Emerging Investigator; Ascending Investigator; Distinguished Investigator; NNF Young Investigator; NNF Laureate Investigator, Investigator Grant in Art History Research, Excellence Project for Young Researchers within Endocrinology and Metabolism, Borregaard Clinical Scientist Fellowship, Research Stipend in General Practice, and Advanced Grant in Endocrinology and Metabolism.

September 2018
Please read “Terms and conditions for grants from the Novo Nordisk Foundation”, that all grant recipients must comply with:

http://www.novonordiskfonden.dk/en/content/conditions-grants

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.