CLINICAL EMERGING INVESTIGATOR 2021

Information and guidelines for applicants

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Information about the call

Grant capital:
Total DKK 40 million

Award amount
Up to DKK 10 million per grant

Application form opens:
October 20, 2020

Application deadline:
January 12, 2021, 2pm (CET)

Applicant notification:
Beginning of March 2021

Interviews:
March 19, 2021 (for selected applicants only)
Beginning of April, 2021 (notification for those selected for interview)

Earliest start date:
May 1, 2021

Latest start date:
February 1, 2022

Review committee:
Committee on Clinical and Translational Medicine

Contact:
Ursula Bach
Senior Grant Manager
E-mail: urba@novo.dk

Kristian Winge
Senior Scientific Manager
E-mail: KWI@novo.dk

1 CLINICAL EMERGING INVESTIGATOR 2021

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

To support and strengthen the development of young and promising clinical research leaders and promote Danish clinical and translational research at a high international level, the Novo Nordisk Foundation seeks to support the starting clinical research leaders with ambitions of combining their clinical work with clinically relevant research.

1.2 THE RESEARCH LEADER PROGRAMME

To support the best and the most talented research leaders at all steps of their careers from start-up to established principle investigators, the foundation offers three specific grants within the 'Research Leader Programme' (schematized below) to stimulate excellence and the possibility to pursue ambitious and original projects. The 'Clinical Research Leader Programme' is targeted the best clinical researchers, who combines, or wishes to combine, clinically relevant research with clinical work and responsibilities. The continued clinical responsibility throughout the project and grant period is essential, as it is considered key to facilitate deep roots of both the research and the researcher in the clinic. The calls 'Emerging', 'Ascending' and 'Distinguished' target principle investigators at specific career-stages and applicants are encouraged to familiarise themselves with the requirements in each call, to ensure they are eligible to apply.
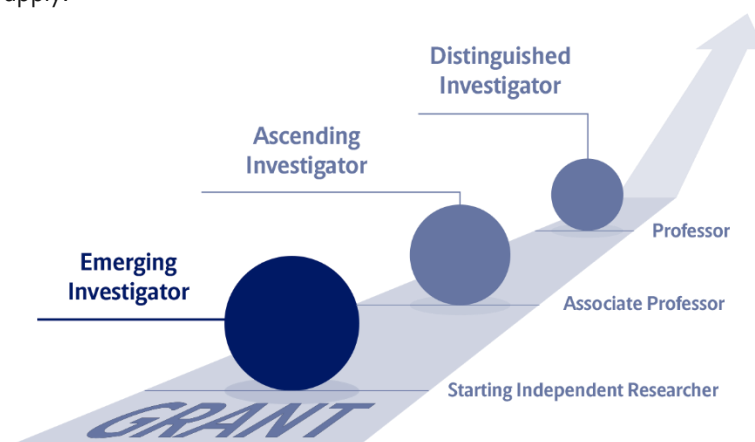
1.3 'CLINICAL EMERGING INVESTIGATOR' PROFILE

The 'Clinical Emerging Investigator' grant is intended for clinicians under medical specialist training, who already has research experience, and who wants to combine his/her clinical work with research. Applicants must commit to dedicate part of their time to research, while extending their medical specialist training, and must apply for part-time substitute replacement salary from parts of the applicant's clinical obligations for five years. Clinical Emerging Investigator grants can also be granted to clinicians who have just finished their medical specialist training, or who are fully qualified to start their medical specialist training.

The grants are designed to support clinical doctors who are building their own research/research group and hence not for clinical researchers who are well established and has a permanent employment.

The grants can be applied for up to 2 years after completed medical specialist training.

Clinical activities in departments must be continued, and therefore the salary for a substitute must be a part of the budget for the young PI to leave for research

1.4 AREAS OF SUPPORT

The overall goal is to support medical research with relevance to patients and human health. The research fields could be within, but are not limited to: Patients and disease related research, translational and clinical research, research in: disease mechanisms; treatment methods; disease trajectories, epidemiology; diagnostic methods; public health and family medicine, intervention studies, register-based research, proof-of concept studies, pilot projects, initial clinical trials and clinical testing, biomedicine etc.

Projects within the field of Bioscience and Basic Biomedicine, should be applied for within the call: 'Hallas-Møller Emerging Investigator – Bioscience and Basic Biomedicine'.

Projects within the field of endocrinology and metabolism, should be applied for within the call: 'Excellence Emerging Investigator Grant within Endocrinology and Metabolism – Nordic Region'.

1.5 ELIGIBILITY

The project must be a 5-year project and it must be anchored at a Danish university, hospital or other non-profit research institution.

- Applicants must have an MD and should have a Ph.D., a dr. med. or similar qualifications.
- Applicants must either be ready to start, be under, or within two years of finishing their medical specialist training. I.e. KBU and the introductory position must be completed if applicants are not yet under medical specialist training. Furthermore, applicants may not be more than two years post-completion of their medical specialist training.
- Applicants must commit to minimum 20% (1 workday) and maximum 60% (3 workdays) research time, leaving from 80% (4 workdays) to 40% (2 workdays) to clinical work at a Danish hospital. The amount of time dedicated to research and clinical work can vary over the five project years, as it best fits the project and applicant. **It must be specified how much time will be spent on research - under the tab 'Applicant Information/'supplementary information'.**
- Applicants must have institutional support from the heads of both the clinical department and the department where the research is to be performed (hosting and support letters **must be uploaded** to the application, please see section 3.4 for further information).

- Upon granting, it is the applicant's responsibility to establish an agreement with the regional council on postgraduate medical training for their individual case.
- 'Clinical Emerging Investigator' grants are individual grants at the disposal of the applicant. If the applied project involves collaboration, the collaboration and the nature of the collaboration should be described in the project description, but the applicant must be the clear driver of the project (**it is not possible to have or register co-applicants for this specific call**).

An applicant may **only submit one application to NNF for an investigator grant** in 2021 within all NNFs funding areas. If you submit more than one, the first application submitted will be evaluated, while subsequent applications will be administratively rejected.

Applications from Master students, Ph.D. students and postdocs **will not be taken into consideration**.

1.6 FUNDING

Each grant must run over five years and can be up to 10 million in total over the five years depending on the time spend / level of commitment from the applicant to the research project.

Applicants must commit to minimum 20% (1 workday) and maximum 60% (3 workdays) research time, leaving from 80% (4 workdays) to 40% (2 workdays) to clinical work at a Danish hospital. The amount of time dedicated to research and clinical work can vary over the five project years, as it best fits the project and applicant. Hence, the time, which the applicant commits to the research project, can vary from project year to project year, going from an average of 1 weekly day to 3 weekly days, depending on how it fits with the continued medical specialist training.

Funding can be requested to cover expenses related to:
- **Salary for the substitute** who will take over PI's clinical responsibilities <u>must be applied for!</u> (clinical activities in departments must be continued, and therefore the salary for a substitute must be a part of the budget for the young PI to leave for research).
- **Salary for research and technical assistance** required for the project, e.g. postdoctoral researchers, PhD students (incl. tuition fee up to DKK 80,000 per budget year, which must be specified/applied for in the budget), technicians and research-year students, etc.
- **Operating expenses**, e.g. lab consumables, chemicals and reagents, bench fee[1], research animals, sequencing/proteomics and other analysis services directly related to the project.
- **Equipment** required for the project, however not exceeding 20% of the total budget.
- **Travel expenses** in relation to the project, i.e. conference and workshop participation and presentation of research results, up to DKK 50,000 per budget year.
- **Other travel expenses** directly related to the project, i.e. experiments carried out in other labs for a limited period.
- **Publication of results** emanating from the research project, up to DKK 25,000 per budget year.
- **Administrative support**, up to 5% of, and included in, the funding applied for.

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

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[1] Bench fees must be specified in the budget, and may only be used for operating expenses, lab consumables, and access to lab space and facilities that cannot be included within another individual budget category. To include a bench fee in the budget, the fee must be part of the general expenses policy of the institute/institution and apply for all employees for which the policy concerns.

- 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:
- Own salary for principal investigator (**it is essential, that applicant's own salary must be covered throughout the entire 5-year project period**)
- Any kind of overhead expenses (e.g. rent, electricity, water, maintenance, etc.).
- Commercial activities

> ⚠️ The grant **may not be used to cover 'overhead'** (i.e. rent, electricity, water, maintenance etc.)
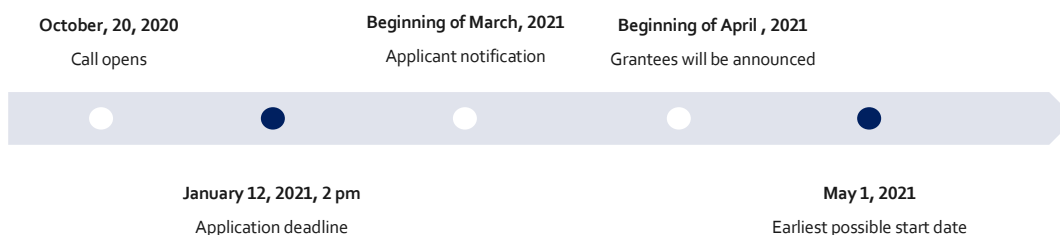
1.7 LANGUAGE
The application and uploads must be written in English (including layman description).

1.8 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.

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

The application system automatically shuts down precisely at 2 pm on the day of the application deadline. It is the applicant's own responsibility to submit the application by this time. We therefore recommend that you press 'submit' well in advance to make sure your application will be taken into considered.

October, 20, 2020	Beginning of March, 2021	Beginning of April , 2021	
Call opens	Applicant notification	Grantees will be announced	
	January 12, 2021, 2 pm		May 1, 2021
	Application deadline		Earliest possible start date

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 noreply@norma.novonordiskfonden.dk to the e-mail address entered on initial registration.

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

1.9   ASSESSMENT CRITERIA

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

Clinical and research profile of the applicant:
- The scientific issue and methods, including to "do 'ability" and impact of the research.
- The collaboration and establishment of a research group.

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 on REGISTER AS APPLICANT. You will be asked to fill in a contact form, which will appear in a new window. The main applicant should only have one user profile. Use your work e-mail address for registration. After the registration, you will receive an e-mail with your user name and password. You can now log in to NORMA. When you log in for the first time, you will be asked to change your password.

Applicants who have previously applied for a grant from NNF or have an active grant may already have a user profile in NORMA. If you are in doubt, an existing user profile can be retrieved by clicking FORGOT

PASSWORD and entering an e-mail address. If you have a user profile in the system, you will receive an e-mail with login information and a new password within 5–10 minutes.

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

To initiate a new application, you first need to identify the call and grant you wish to apply for. In NORMA, go to the OPEN CALLS tab, which is located in the upper right corner of the screen. All currently available grants are visible in tabs that are sorted by NNF's overall grant areas.

Initiate an application by clicking the blue APPLY NOW button. Your draft application is then created and will remain a draft version until you actively submit the application.

You can create and subsequently edit a draft version of the application until the deadline. A draft application can be saved by clicking SAVE DRAFT and may be cancelled at any time up to the deadline by clicking the button CANCEL APPLICATION. An application is not submitted to NNF until an applicant has clicked SUBMIT.

The application comprises tabbed sheets that need to be completed but not necessarily in chronological order. Fields marked with a red star (*) are obligatory to fill in.

You can review the application at any time by clicking OPEN under MY APPLICATIONS on the NORMA front page. The whole application, including any currently entered data, can be downloaded as a PDF file by clicking on APPLICATION PDF. Make sure the PDF is readable and formatted appropriately before submitting your application.

2.3   TEXT AND ILLUSTRATIONS

FILLING IN THE FIELDS
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.

APPLICATION TEXTS

Text from Word, for example, can be copied and pasted into most text fields of the application. It is, however, important to check that formatting, special letters and symbols have not been converted or lost in the text fields after copying and pasting. If the formatting looks wrong in NORMA and in the PDF, you can try to change all text to "Normal" under the tab FORMAT.

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

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

ILLUSTRATIONS

Illustrations with figures, charts, tables, images etc. related to the project description can be uploaded under PROJECT INFORMATION (a maximum of four illustrations are allowed). Include the illustration number and a legend or caption for each illustration file when uploading. The illustrations will be integrated in the final application PDF.

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.

All applicants must read and accept NNF's Standards for Good Research Practice before submitting the application. A link can be found under "Policies" in the top right corner of the window. 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. Fields in the application that are incorrectly completed or incomplete will be listed in a box at the top of the screen. Clicking on each individual line marked in red takes you directly to the incomplete field. The box will disappear when you select SAVE DRAFT. This allows you to continue with the application and submission.

> ⚠ A list of any incorrect or incomplete entries will be autogenerated when you click SUBMIT. Amending incorrect or incomplete entries can be time-consuming, so we recommend submitting applications well before the deadline.

If you wish to modify a submitted application before the deadline, it is possible to reopen the application. Be aware that the application must be resubmitted before the deadline. Applications cannot be modified after the submission deadline.

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 (please check your spam folder), you should contact NNF as soon as possible using the contact details on page 3.

If you wish to withdraw a submitted application after the deadline, you must contact NNF via e-mail, using the contact information on page 3.

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

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 INFORMATION

Enter information on the main applicant and administrating institution in the following tabbed sheets:
- Personal information
- Current institution
- Educational information
- Administrating institution
- Applicant information

⚠️ 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.

MAIN APPLICANT
It is essential, that applicant's own salary must be covered throughout the entire 5-year project period.

Clinical activities in departments must be continued, and therefore the salary for a substitute must be a part of the budget for the young PI to leave for research.

Your salary is a part of your employment and track in your specialist training and specialized job after finishing the training.

CO-APPLICANT(S)
It is not possible to have or register co-applicants for this specific call.

⚠️ Please note that it is not possible to have or register co-applicants for this specific call.

3.2   PROJECT INFORMATION

Enter a description of the project under the PROJECT INFORMATION tab. A maximum of four illustrations can be uploaded here.

GRANT PERIOD
After you enter the start and end dates for the grant, NORMA generates a grant period in whole years. The grant period is the duration of NNF's grant for the project.

PROJECT TITLE
Please provide a short title for the project (maximum 150 characters, including spaces).

BRIEF PROJECT DESCRIPTION
Please provide a brief stand-alone summary of the project describing its purpose, target group and activities. (maximum 2,000 characters, including spaces).

PROJECT DESCRIPTION
Can be a maximum of 30,000 characters (including spaces, line breaks and special characters). Please describe your proposed research project in detail – including purpose, background, methods, collaborations and the significance of the project. Up to four illustrations can be uploaded to the project description.

CV
Can be maximum 4,000 characters (including spaces, line breaks and special characters). Please include in your CV 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 your CV an overview of current grants and indicate how much of your research time (in %) is committed to each of the projects.

LITERATURE 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).

PUBLICATION LIST
Please only include the 10 most relevant publications for evaluating your merits. Include a complete specification of all authors for each publication with your own name highlighted.
Applicants are strongly encouraged to provide a full list of publications in ORCID.

LAY PROJECT DESCRIPTION
In English (maximum 1,000 characters, including spaces, line breaks and special characters). 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 and no confidential information should therefore be included in this section.

ADMINISTRAING INSTITUTION
For 'Clinical Emerging Investigator' grants, it is a requirement that the administrating institution is the institution where the research project will be carried out. The clinical department where the applicant will be part-time associated (i.e. where the applicant is employed), can only be administrating institution, if the research project is carried out at the same department.

SUPPLEMENTARY INFORMATION (under the 'Applicant information' tab)
Please describe clearly how you intend to combine research with your continued medical training, and how your commitment to the applied research project will extend your medical specialist training. Also

describe your terms of employment, your current clinical responsibilities and how and to what extend these will be continued during the project period.

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

3.3 BUDGET

The budget only comprises the information entered in the BUDGET tab. Additional budget information attached under UPLOADS or added under other tabs than BUDGET will not be considered.

Before you begin to fill in the budget template, enter GRANT PERIOD START DATE and GRANT PERIOD END DATE under the PROJECT INFORMATION tab and press SAVE DRAFT.

The budget must be entered in budget years following the grant period and not calendar years.

Complete the budget as follows:
* Click on the blue OPEN/EDIT icon to open a budget in a pop-up window.
* Click the + key to add budget rows.
* Select one of the budget headings, enter an amount under VALUE (DKK) and specify what the amount is for under DESCRIPTION.
* All amounts must be stated in Danish kroner (DKK) without decimal points, commas or spaces. NORMA automatically inserts the thousands separator.
* Save and close the budget spreadsheet by clicking SAVE and CLOSE (in that order) and then return to the BUDGET tab.

Important: If you make any changes to the grant period after filling out the budget, you must clear the budget table before making the change to the grant period.

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

Funding, both received and applied for, from the applicant's own organisation and from other sources should be entered under ADDITIONAL CONTRIBUTIONS FOR THE PROJECT. The amount entered should be the total sum for the entire grant period. The NNF does not allow double funding and there can be no budgetary overlaps between projects. The INFORMATION FOR ADDITIONAL CONTRIBUTIONS field must clearly describe what the additional contributions cover and how the project proposed in this application is different from the project already funded or applied for from other parties than NNF. If the applicant, after submitting the application, receives funding for the project or parts of the applied project from others, the NNF must be contacted as soon as possible.

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

3.4   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.

Two attachments must be uploaded to the application before submission:

1)   A 'SUPPORT LETTER' signed by the head of the clinical department, where the applicant is currently employed (has his/her main employment), accepting that the applicant can be granted part-time release from his/her clinical responsibilities and that the medical specialist training will be extended. The head should also state in this letter that the applicant will remain part-time affiliated with the clinic during the entire project period. In case the applicant has not yet started medical specialist training, a documentation that KBU and the introductory position has been completed must be uploaded instead (as a merged pdf).

2)   A 'HOSTING LETTER' signed by the head of the department, where the research will take place, accepting the applicants proposed research project to take place at the institute, that the department will provide the required infrastructure such as laboratory and office space, and that the budget applied for will be administrated and used as indicated in the application.

Please be aware that in the case the research is to be conducted at the place of clinical employment of the applicant, two letters are still required to be uploaded before the application can be submitted, even though they, in this case, will be signed by the same head.

Further, if more documents are uploaded than the two required (Hosting and Support Letters) they will be deleted from the application before the application is send for assessment.

3.5   PREVIOUS AND CURRENT GRANTS FROM THE FOUNDATION

If you 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.

If you have previously submitted other applications in the same calendar year, summarize how these applications are related to the current application.

October 15, 2020

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.