



CHALLENGE PROGRAMME 2025

Heterogeneity in biomanufacturing

Information and guidelines for applicants

Table of contents

1	CHALLENGE PROGRAMME 2025 - Heterogeneity in biomanufacturing	4
1.1	PURPOSE	4
1.2	AREAS OF SUPPORT	4
1.3	ELIGIBILITY	6
1.4	DIALOGUE MEETINGS AND THEMATIC SYMPOSIUM	6
1.5	FUNDING	6
1.6	LANGUAGE	7
1.7	APPLICATION PROCESS	7
1.8	ASSESSMENT CRITERIA	8
2	THE APPLICATION AND GRANT MANAGEMENT SYSTEM – NORMA	8
2.1	USER REGISTRATION	8
2.2	CREATING AN APPLICATION	9
2.3	TEXT AND ILLUSTRATIONS	9
2.4	SUBMITTING THE APPLICATION	10
3	APPLICATION CONTENT	11
3.1	APPLICANT	11
3.2	INSTITUTION	12
3.3	PROPOSAL	12
3.4	BUDGET	13
3.5	APPENDICES	16

Information about the call

Grant capital: DKK 120 million

Award amount: Up to approx. DKK 10 million per year over 6 years, for a total budget of DKK 30-60 million per grant

Application form opens: 9 April 2024

Application deadline: 9 October 2024

Applicant notification: Stage 1: December 2024 Stage 2: June 2025

Earliest start date: 1 August 2025

Latest start date: 1 July 2026

Review committee:

Applications will be evaluated by an independent, international committee of scientific experts. The committees will be posted on the Novo Nordisk Foundation website

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1 CHALLENGE PROGRAMME 2025 -Heterogeneity in biomanufacturing

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.

- Section 1 describes the overall frame and conditions of the call, eligibility criteria, and evaluation process.
- Section 2 provides technical guidance for how to access and navigate in the application and grant management system NORMA.
- Section 3 gives essential information regarding the application content, structure, and budget.

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.

1.1 PURPOSE

The purpose of the NNF Challenge Programme is to make a substantial contribution to the development of Danish research ecosystems within strategically relevant research areas. The aim is to give leading researchers the opportunity to assemble a strong team that can collaborate in a centre-like structure with a unifying vision and mission to develop solutions to major challenges. The Programme provides long-term funding to enable scientific depth and focus and facilitate synergy between the research partners.

1.2 AREAS OF SUPPORT

The programme is a strategic effort targeting specific challenges within annually selected research themes. For the 2025 application call, the Challenge Programme is seeking to support the following research theme:

• Heterogeneity in biomanufacturing

The challenge is to understand the impact of heterogeneity in biomanufacturing and develop novel approaches for detection, control, and mitigation throughout both upstream and downstream processing. Research must aim to enhance process performance with an emphasis on increasing yield, titre, purity, and productivity, and enable economically viable scaling of disruptive solutions that minimize environmental footprints, save energy, and conserve natural resources. The programme is aimed at fundamental and applied research that merges synthetic biology, microbiology, process engineering, and analytical or digital methodologies to gain insight and develop tools or methods with potential for broad applicability. Research must aim to integrate techno-economic analysis and environmental sustainability impact assessment when relevant. Variability in biomanufacturing often stems from genetic instability within microbial populations or the complex nature of influents and effluents. Such heterogeneity can impact the efficiency of bioreactors and the recovery of products. Gaining a deeper understanding of heterogeneity in biomanufacturing with emerging technologies could surface opportunities that enhance economic competitiveness of sustainable bio-based solutions, allow use of alternative, non-conventional feedstocks, and accelerate society's green transition.

The research must be interdisciplinary in nature. Any research methodology or discipline can be included, provided the research incorporates a clear and significant element of biomanufacturing. Research should enable solutions applicable for large volume production of food, ingredients, materials, energy carriers, or other related biomanufacturing sectors. Research can explore pure microbial systems or consortia under aerobic or anaerobic conditions, and may include batch, fed-batch, or continuous processes. While sugar-based fermentation substrates are in scope, gaseous and waste feedstock utilization is encouraged. The Novo Nordisk Foundation highly values integrating data science with biomanufacturing and strongly recommends a clear data science component in the research. Research offering substantial advancements in process performance or cost efficiency at scale will be considered; incremental improvements are not sufficient for broad applicability or impact. Microbial strain development cannot be the primary focus of the research but can be included. Use of mammalian cells for products such as cultivated meat, cell-based milk, or biopharmaceuticals is not in scope. The programme does not include development of specific end-products.

Supported research may include but is not limited to:

- Exploring and modelling microbial responses to bioproduction heterogeneity, e.g., for a deeper understanding of metabolic and genetic regulatory networks, the use of waste as a feedstock, or strategies for enhancing microbe resilience to process fluctuations during scale-up.
- Development of novel bioreactor designs or other systems engineering to overcome heterogeneous gas-liquid mass transfer, reduce nutrient starvation or high osmotic stress zones, or reduce pH or substrate gradients, e.g., with pelleting, or mixing systems for biomanufacturing of bulk food ingredients or other bioproducts.
- Development of unit operations and new materials for product recovery and purification that reduce the need for excessive, undesired treatment of bioreactor effluents or adapt physicochemical properties of fermentation broths, e.g., with green solvents, or centrifugal pump impeller systems.
- Development of computational tools to predict gradients, reduce heterogeneity, understand the effect of oscillations on cell factories, or re-think automated production workflows, e.g., integrating computational fluid dynamics with metabolic modelling, population balance modelling, or single-cell analytics.
- Development of process analytical technology tools for real-time detection, measurement, and control of deviations in raw materials, bioreactors, or during product recovery, e.g., using spectroscopy, mass spectrometry, solid-liquid separation technologies, sensors, digital twins, or other data analytics for inter- and intra-batch variations, inoculum transfers, or the removal of toxicants, contaminants, and byproducts.
- Development of downscaling tools to predict process performance and reduce the risks of process failures when scaling up to larger production volumes.

1.3 ELIGIBILITY

The Challenge Programme supports excellent research leaders from 2-4 research groups (main applicant plus 1-3 co-applicants).

The programme leader must be at least 75% employed at a Danish university, hospital or other non-profit research organization, that will be considered the host institution of the project. Affiliation must be declared in the hosting letter and justified if less than 75%.

The research institutions of the co-applicants can be located in Denmark or abroad. The coapplicants should contribute significantly to the advancement of the project and should receive part of the funding.

Industry collaboration is possible; however, funding cannot be awarded to industrial partner(s).

General rules for applications:

- a. Being the recipient of another Novo Nordisk foundation research grant does not preclude receiving a Challenge Programme grant.
- b. Holders of an active Challenge Programme grant may apply for a new Challenge Programme grant during the final year of the grant; however, a new Challenge grant cannot be activated until the existing grant is completed and no longer active.
- c. 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 must be contacted immediately.
- Please refer to our general terms and conditions (<u>http://www.novonordiskfonden.dk/en/content/conditions-grants</u>) for further information that apply when applying for/receiving a grant from NNF.

1.4 DIALOGUE MEETINGS AND THEMATIC SYMPOSIUM

To follow the progress of the individual Challenge research programmes, the Foundation will hold dialogue meetings with grant recipients every second year. Grant recipients will receive information regarding the timeline and format of these meetings.

To facilitate network building and knowledge-sharing, the grant recipients within each theme are expected, together, to facilitate one thematic symposium during the grant period, ideally in year 3 or year 4. The Foundation will provide a separate budget and cover the costs of the symposia (up to DKK 250.000).

Please note: This symposium should not be included in the application budget.

1.5 FUNDING

The total grant budget for this theme is up to DKK 120 million.

For each grant, up to approx. DKK 10 million can be awarded per year, over a 6-year grant period, for a total budget of up to DKK 30-60 million per grant.

The grant cannot be used to cover the main applicant's or the co-applicant's own salary.

Applicants may apply for funding for the following types of expenses (see section 3.4 for details):

- Salary for scientific, technical, and administrative staff
- Tuition fee for PhD students
- Operating expenses
- Equipment
- Infrastructure establishment and installation
- Publications costs
- Communication
- Travel expenses
- Collaborative activities
- Conference participation
- Bench fee
- Direct administrative expenses (up to 5% of the total budget applied for).

NNF will not award funding for:

- commercial activities
- overhead (i.e., rent, electricity, water, maintenance, etc.)

1.6 LANGUAGE

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

1.7 APPLICATION PROCESS

The application process consists of 2 stages. **Stage 1** consists of a short expression of interest and does not contain a detailed budget. A number of shortlisted applicants will be invited to **Stage 2**, in which the applicants will be asked to submit a comprehensive application with a detailed project proposal of up to 30,000 characters. See section 3.3 for detailed instructions on content.

As a part of the **Stage 2** evaluation, the main applicants will be invited to the Novo Nordisk Foundation to present and discuss their proposed research projects with the review committee.



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 <u>norma-noreply@novo.dk</u> to the e-mail address entered on initial registration.



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

1.8 ASSESSMENT CRITERIA

Applications will be evaluated by an independent, international committee of scientific experts. The selection of the successful Challenge Programme applicants will be based on the following criteria:

- scientific excellence, originality, and potential impact,
- feasibility of the project and suitability of the proposed centre setup,
- the leadership qualifications of the main applicant,
- the financial situation and prior obligations of the applicants, in case it can compromise the dedication to, and quality of, the proposed work, and
- strategic outlook and link to overall challenge.

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). If you are the holder of an active Challenge grant, please be aware of the general rules for applications listed in Sec. 1.3.

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: <u>https://norma.novonordiskfonden.dk</u>

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: <u>norma-support@novo.dk</u>.



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 email. 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 <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 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. However, it is the responsibility of the main applicant to ensure that the application in all its parts adheres to the guidelines.

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 information about all those involved with an application. For this call, it means the main applicant and 1-3 number of co-applicants. 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.

Information about each applicant is collected through individual tasks in the APPLICANT DETAILSsection, detailing experience, publication history, application history with NNF, etc. After filling in all mandatory fields, the applicant should **complete** the task to save the details.

The **main applicant** is the responsible party for the application and can enter their details through the Applicant Details-task with the type 'Applicant'.

Co-applicants must be invited through NORMA and subsequently enter their details through the APPLICANT DETAILS-task with the type 'co-Applicant' in the system. Please follow the instructions in NORMA on how to invite co-applicants to your application. When the coapplicant 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.



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

The following information about each applicant is mandatory and is collected through individual tasks in the APPLICANT DETAILS-section:

• **CV:** Can be a maximum of 4,000 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, h-index.

- **Publication list**: Can be a maximum of 5,000 characters. Provide a link to an updated profile with a full publication list on, e.g., ORCID, Google Scholar, Web of Science, or Scopus. Please also 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.
- **Summary of own research:** Can be a maximum of 2,000 characters. Please provide an outline of your research focus and main contributions and achievements relevant for the present application.
- **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 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.

Co-applicants will only be able to edit their own APPLICANT DETAILS-task, as well as make changes to the main application but cannot submit the application. The main applicant, on the other hand, can review and edit all Applicant Details-tasks for the application including those for co-applicants.



Before the application can be submitted, the main and co-applicants must save and complete their own details by clicking on COMPLETE TASK under their individual APPLICANT DETAILS-section.

3.2 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.

3.3 PROPOSAL

Describe the project using the fields on the PROPOSAL tab.

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 2000 characters, including spaces).

PROJECT DESCRIPTION

<u>The Stage 1 project description</u> is a short expression of interest (limited to 10,000 characters including spaces, line breaks and special characters), which should describe:

- The proposed research, including its relevance for the theme and hypotheses to be addressed.
- The project's originality, ambition, and expected outcome.
- An outline of how the research groups will collaborate, and how this is foreseen to be particularly well suited to address the proposed challenge.
- The roles of the participating PIs and their research groups.

<u>The Stage 2 project description:</u> Several shortlisted applicants will be invited to Stage 2, in which case the NORMA interface will open a new tab (PROPOSAL), where the applicants must enter a detailed project proposal of up to 30,000 characters. This full application should include descriptions of:

- An extensive, detailed research proposal. Includes purpose, background, methods, and the significance of the project.
- A description of the involved research groups and their roles and plans for national and international research collaboration and partnerships.
- Plans for ensuring the establishment of a learning environment able to foster the next generation of outstanding researchers.
- A detailed account of the proposed governance and organisational structure of the project.

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



Please note that the application should address all the assessment criteria listed in subsection 1.8.

3.4 BUDGET

A detailed budget is **not** required for **Stage 1** application. However, please indicate the approximate total requested amount, the total additional contributions, and the total project cost in the Norma system.

A detailed budget is required for **Stage 2** applications. This budget should clearly indicate the co-applicants share of the total 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.

ELIGIBLE BUDGET COSTS

Applicants may apply for funding for the following types of expenses when directly related to the project:

- **Salary** for technicians, bioanalysts, 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 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.
- **Collaborative activities**: Other travel expenses that are directly related to the project, e.g. workshops, meetings, exchange, seminars, other efforts directed at ensuring fruitful collaboration between the partners of the programme, and for experiments carried out in other labs for a limited period of time.
- **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** provided it is essential for the proposed project and its use after completion of the project can be clearly justified. NB: Equipment purchased at expenses above DKK 100,000, should be located at the host institution both during and after the project period. Applicants can request to place the equipment at the co-applicant's premises, but it must be addressed and justified in the application.

- **Infrastructure** required for the project. Infrastructure funded by the grant must be located at the host institution both during and after the project period. Free/excess capacity for the infrastructure must be made available to the wider research community.
- **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. Subcontractor cost.
- **Bench fees** 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. The budget must specify the expenses covered by the bench fees, 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 fees 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. An unspecified bench fee without documentation will not be accepted. Maximum DKK 8,000 per month per full-time equivalents (FTE) working on the project is acceptable for this post. Documentation that the administrating/co-applicant's institution has a general bench fee policy should be available at the time of application and must be provided upon request.

- **Direct administrative expenses** (up to 5% of the overall budget and included in the budget) to cover administrative expenses directly related to the project:
 - can cover expenses such as accounting, payment of salaries, purchasing, hiring, as well as auditing and financial reporting on the project.
 - o cannot cover administrative expenses that are not directly related to the project.
 - is not automatically included in the grant and must be stated/applied for in the application budget but should not be specified in detail.
 - can via the host institution be shared between the institutions of the main- and co-applicant(s).

Please make sure it is clear which of the applicants each expense is dedicated to.

Please provide a high-level overview of the budget in the SUPPLEMENTARY INFORMATION field, explaining the distribution of funds among the collaborators and activities.

FULL-TIME EQUIVALENTS (FTE)

For salary items, the number of full-time equivalents in years must be stated in the field FTE. There are 1924 gross hours in a year, from where non-working days must be deducted.

EXAMPLE: 6 weeks of holidays (222 hours), 10 public holidays (74 hours) 10 educational days (74 hours) deducted from 1924 amounts to 1554 net hours per year. To find the FTE for e.g., 30

hours, the calculation should be: 30 (hours) / 1554 (net hours) = 0.02, which is what should be stated in the FTE field.

Budget item (illustrative purposes only)		Description (illustrative purposes only)
Salary – PhD		PhD (1 person-year full time)
Salary – project employees		Project staff (2 x 60 hours)
Salary – TAP		Technical staff 2.5 person months full time



Applicants may only apply for the types of expenses listed in subsection 1.5.

3.5 **APPENDICES**

Mandatory uploads – only for Stage 2

Signed letter of commitment from the Danish host institution, taking responsibility to host the project and administrate the grant (*Hosting letter*).

Please *do not attach* other appendices such as recommendations, support letter from collaborators, offers on equipment, etc.

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.

April 2024

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.

