BI BioInnovation Institute

BIOINNOVATION INSTITUTE PRESEED PROGRAM

GRANTS FOR RESEARCH INSTITUTIONS

Information and guidelines for applicants

March 2020

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Grant information

Funding:
Up to DKK 3.5 M per project

Call opens:
March 18, 2020

Application deadline:
June 4, 2020, 2 pm

Pitch day for invited applicants:
September 2 and 3, 2020

Applicant notification:
September 2020

Earliest start date:
November 2020

Latest start date:
November 2021

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1 THE PRESEED PROGRAM

1.1 PURPOSE

The BioInnovation Institute's (BII) PreSeed Program issues grants or convertible loans for risk free maturation of research-based innovation that is carried out at either Nordic[1] research institutions or Danish-based life-science start-ups. The objective is to address early stage technical and commercial risks. The goal is to accelerate the scientific maturity of the innovation in order to attract further funding that can bring new solutions and products to the market. In addition, the BII can prepare PreSeed recipients for further fundraising by helping with team development and commercial analysis.

These guidelines are written for research institution applicants. If you wish to apply as a start-up, please refer to specific guidelines on https://bioinnovationinstitute.com/preseed/

1.2 RESEARCH FIELDS

The PreSeed Program supports innovative life science projects within therapeutics, bioindustrials and medical technologies. A typical project would have already shown preliminary proof of concept. This could have been through a smaller translational funding award and/or academic funding.

BII funding is normally aimed at projects that can raise funds from professional investors or industrial partners following our programs. We do however encourage applications from projects addressing novel approaches to treatment of anti-microbial resistant pathogens that could raise significant amounts of alternative financing to enter clinical testing.

1.3 ELIGIBILITY

ELIGIBILITY FOR RESEARCH INSTITUTIONS

- Applicants must have obtained a master's degree in the field of life science research or an equivalent qualification at the time of application.
- The applicants can be faculty members, researchers or employees based at universities, hospitals or other research institutes in the Nordics.
- Associated with the application a housing agreement (see section 3.4 Mandatory uploads) covering the grant period must be submitted from the host institution.
- The applicant must present a plan for IPR in the event of commercial spinout.
- If the project has co-applicants from multiple research institutions, an IP management agreement between institutions must be in place.

LIMITATIONS FOR RESEARCH INSTITUTIONS

- An applicant may submit only one application per call.
- A research group may submit only one application for activities related to the same project per call.

[1] The Nordic region is Denmark, Sweden, Norway, Finland and Iceland.

- An applicant/research group is not allowed to hold multiple grants at the same time for overlapping activities. See 'Section 3.3 Budget' for additional information.
- If the project has already received a PreSeed grant from Novo Seeds, application for this call is not possible.

Please read "Terms and conditions for BioInnovation Institute" before submitting an application: https://bioinnovationinstitute.com/wp-content/uploads/BII-Terms-and-conditions-UPDATE-November-2019.pdf

1.4 FUNDING

The PreSeed program provides research institutions with grants. Each grant is up to DKK 3.5 million paid in tranches. The first tranche is paid upon project initiation while payment of subsequent tranches is based on fulfillment of predefined milestones that can be a mix of both technical and commercial milestones. The project can run for a maximum period of up to 18 months.

The grant can cover expenses such as:

- Research activities, e.g. consumables, testing and experiments that strengthen the commercial potential of the project idea/invention, CRO activities, use of university core facilities
- Development of MVP, prototypes and chemistry, etc.
- Salary for staff (not for applicant)
- Consultants
- Publications
- Fees associated with the prosecution and maintenance of intellectual property
- Regulatory strategy and compliance
- Team member education
- Commercialization costs e.g. market analysis
- Travel costs where appropriate, which includes the participation in BII events
- Administrative support (maximum 5% of the total budget)

Administrative support:

- Can cover expenses such as accounting, administration related to 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
- Is not automatically included in the grant and must be stated/applied for in the application budget but should not be specified in detail

Expenses not covered by the grant:

- Overhead (e.g. rent, electricity, water, maintenance, etc.)
- Apparatus and larger devices (unless subject to prior agreement)

1.5 LANGUAGE

The application and all uploads must be in English.

1.6 APPLICATION PROCESS

BII engages experts and life science investors to help evaluate the proposals. Chosen projects will undergo external due diligence for commercial potential, scientific quality and regulatory path to market. Selected projects will be invited to pitch in front of the BII business development team and BII Advisory Group; a mix of professionals from research, large industry and venture capital. The Advisory Group will evaluate if the funding will make a significant impact on the commercial viability of the proposed project

The evaluation will be based around the following criteria:

- Significance and originality of the idea
- Quality of the scientific data
- Commercial potential e.g. impact, time to market
- The skills and qualifications of the applying project team and their ability to further progress the project
- The IPR, legal and regulatory strategy
- Further funding strategy – what stage will the project be at upon completion of the PreSeed program and will it be able to secure further dilutive or non-dilutive funding?

The BII Board of Directors makes the final decision based on the recommendations from the BII team informed by the due diligence and feedback of the BII Advisory Group.

1.7 SCIENTIFIC REPORTING

Grant recipients are required to report annually on their scientific and where relevant commercial activities through the online tool Researchfish. This is used as one of multiple sources to generate the Novo Nordisk Foundation's impact assessment. Further information on reporting requirements will be provided for the participating companies and research institutions once selected.

1.8 FINANCIAL REPORTING

During the program, the BII team will assess whether the funding tranches have been spent in accordance with the budget and milestone plan.

1.9 BEING PART OF THE BII COMMUNITY

BII believes our value lies in more than the money we provide. We expect an ongoing dialogue with PreSeed projects to help you achieve your milestones and post PreSeed funding. You will be expected to attend regular meetings with the BII team and participate in relevant activities.

2 THE NOVO NORDISK FOUNDATION APPLICATION SYSTEM – NORMA

Sections 2 and 3 provide guidance on completing and submitting an application through the Novo Nordisk Foundation (NNF) online application and grant management system NORMA. Section 2 contains general technical information, while section 3 contains information specific to this call.

2.1 USER REGISTRATION

NORMA can be accessed directly at: https://norma.novonordiskfonden.dk

If you do not have a user profile in NORMA, you can register by clicking REGISTER AS APPLICANT. 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. If you have a user profile in the system, you will receive an e-mail with login information and a new password within a few minutes.

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

2.2 CREATING AN APPLICATION

To initiate a new application, go to the OPEN CALLS tab located in the upper right corner of the screen. Navigate to BIOINNOVATION INSTITUTE. Initiate an application by clicking the APPLY NOW button.

Your draft application is created and will remain a draft version until you actively submit the application. After submission, it is still possible to reopen and edit the application. However, you are responsible for re-submitting before the deadline. The application comprises of 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 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.

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

2.3 TEXT AND ILLUSTRATIONS

APPLICATION TEXTS

Text from e.g. Word 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. Available functions for formatting text are at the top of

the text fields. Some shorter text fields do not have the option to format. Please use standard fonts and font size 11-12.

ILLUSTRATIONS

In the PROJECT INFORMATION tab, a maximum of four illustrations with figures/charts/tables/images, etc. related to the project description can be uploaded. Include illustration number and 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, BMP. The maximum accepted size for each illustration is 1050*1650 pixels.

2.4 SUBMITTING THE APPLICATION

The application must be submitted via NORMA. It is not possible to submit the application, or any part of it, by ordinary mail or e-mail. Any material submitted outside the application system will not be included in the evaluation.

All applicants must read and accept NNF's Standards for Good Research Practice before submitting the application. A link can be found in the top right corner of NORMA next to your name. 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. Incorrectly completed fields will be listed in a pink box at the top of the application. Clicking on each individual line marked in red takes you directly to the incomplete field. The pink 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 e-mail will be sent to the applicant. If you do not receive a confirmation of receipt (please check your spam folder), you should contact BII as soon as possible using the contact details on page 3. If you wish to withdraw a submitted application after the deadline, you must also contact BII via e-mail.

All applicant and application information will be treated confidentially.

Remember to check that the PDF version of the application is readable and contains all entered information and uploads before submitting the application.

3 APPLICATION CONTENT

This section provides guidelines on the content required in the various sections of the online application form. In NORMA you will see tabs under which you must provide the following information:

3.1 APPLICANT INFORMATION

Enter information on the main applicant and administrating institution in the following tabbed sheets:

- Personal information (name, email, phone, gender, position, nationality, residential country, date of birth, country of residence, ORCID)
- Current institution (institution name, phone number, city and country)
- Educational information (highest degree attained, institution, date of degree)
- Administrating institution (institution name, department/institute, phone number, city, country)
- Applicant information:
    - CV: max. 4,000 characters including spaces (alternatively you can upload your CV).
    - Publications (10 most relevant publications): please provide a complete specification of authors for each publication with your own name highlighted. Applicants are strongly encouraged to provide a full list of publications in ORCID.
    - Summary of own research: please summarize your own research which is of relevance to this application.
- CO-APPLICANTS (see elaborate information below).

CO-APPLICANT(S)

For this call, co-applicants are allowed for research institutions. 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. They must be invited through NORMA and subsequently confirm their status as co-applicants in the application.

- Go to the INVITATIONS link in the blue field on the left
- Click the + symbol and enter the name and e-mail address of the co-applicant
- Select CO-APPLICANT under ROLE in the drop-down menu
- Click INVITE
- Co-applicants will be contacted automatically and asked to confirm their status as co-applicants

When the co-applicant accepts the status as co-applicant, additional fields will appear in the application. The CO-APPLICANT field includes information about co-applicant(s), including previous grants received from NNF. A short CV (maximum two pages) or an endorsement from the institution for each co-applicant can also be uploaded as a PDF file by clicking on CO-APPLICANT UPLOAD(S). Either the co-applicant or the main applicant must complete the CO-APPLICANT field. Only one person can edit the application at a time.

If the co-applicant has confirmed participation but the information has not been entered in the CO-APPLICANT field NORMA will not include the co-applicant as part of the application. The main applicant must therefore check that the information about any co-applicant(s) is included in the application before submitting it.

Please start the process of inviting co-applicants well in advance of submission deadline.

3.2 PROJECT INFORMATION

In the PROJECT INFORMATION tab, you will provide information on the following:

GRANT PERIOD

After you enter the start and end date for the grant, NORMA generates a grant period in whole years. The grant period is the duration of BII's funding for the project. See page 3 for earliest possible start date. The maximum allowed project period is 18 months.

PROJECT TITLE

Please provide a short title for the project. The title will be published if the application is granted so please don't include confidential information (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. Please also specify your research area (therapeutics, bioindustrials or MedTech) (maximum 2,000 characters including spaces).

MANDATORY SLIDE DECK

Please provide a quality slide deck of maximum 30 slides under the tab UPLOADS. The slide deck is one of the most important elements of the application and *could* cover some of the following topics:

Problem

1. Describe the problem you aim to solve.

Solution

2. *Solution*: Describe how you will solve the problem.
3. *Impact*: Describe how your solution creates significant impact for society, people and/or patients.
4. *Best in class*: Describe how your technology is superior to current available solutions.

Scientific rationale

5. *Science*: Describe the crucial underpinning scientific evidence to support your solution and how this reaches beyond the current state-of-the-art.
6. *Milestones*: Present most recent milestones (Proof of Concept) underpinned by your data.
7. *Next step*: Explain what data is yet to be generated – what is your killer experiment?

Clinical challenges – where applicable

8. What is the target clinical indication, treatment modality and the challenges of accessing this patient group.

Industrial challenges – where applicable

9. Describe the desired yield, cost target, and upscale and downstream processes.

Business model and market

10. *Commercialisation*: Describe your business model, pricing strategy (e.g. cost of goods, unit economics) and commercialisation strategy.
11. *Development plan:* Provide an overview of 3-5 most important scientific and commercial milestones (GANTT chart).

12. *Customer identification*: Describe potential customers and users of your solution – and how you intend to reach them.
13. *Commercial partners:* Explain how you have demonstrated partner interest to date – e.g. industry experts or other KOLs.
14. *Regulatory strategy:* Describe the regulatory strategy for your product emphasizing the requirements to reach market.
15. *Reimbursement:* If relevant, demonstrate the reimbursement situation for your product.

Competitor landscape

16. List most relevant competitors and/or alternative solutions e.g. in a competitor matrix.

Risk analysis and mitigation strategy:

17. Account for the project risks (e.g. scientific, technical, legal, regulatory, commercial) and present a risk mitigation strategy.

Team

18. *Project team*: Provide an overview of the project team and their scientific and commercial competencies.
19. *Gaps*: Describe the gaps in the competences of the team and how these will be addressed. In particular with regards to experience in raising VC financing and developing products in an industrial setting.

Intellectual property and freedom to operate

20. *Current IP*: Describe existing enabling relevant IP and where relevant highlight key licensing terms. Additionally, describe any third-party IP that may be requires for the successful completion of the project. Where possible, provide a summary of freedom to operate or international search reports that may have been completed.
21. *New IP*: Describe your plan for protecting new IP generated in the project and where relevant, how it will be managed among partners.

Next steps

22. *Exit strategy and future funding requirements*: Provide a draft vision for the company following the PreSeed Program i.e. what kind of external funding and additional maturity activities are expected for growth of the project/company.
23. *Market entry*: Estimate your time to market including funding requirements for each stage of development.

PROJECT DESCRIPTION

The project description must cover, but is not limited to, the same elements mentioned above (maximum 5,000 characters including spaces).

ILLUSTRATIONS

A maximum of four illustrations related to the project description (JPG, JPEG, BMP or PNG) can be uploaded here.

LITERATURE REFERENCES

Provide reference information for literature cited in the project description above (maximum 4,000 characters including spaces).

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

TYPE OF RESEARCH
1-2 choices allowed, choose the most fitting one.

RESEARCH METHODS
1-3 choices allowed, choose the primary methods/subjects.

3.3 BUDGET

Before you begin to fill in the budget, enter GRANT PERIOD START DATE and GRANT PERIOD END DATE (max 18 months) 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.

The application must include a detailed budget linked to the scientific and commercial development milestones. Please enter your budget for all activities you expect to undertake during the PreSeed Program. It is important that each budget post is carefully described. For example, if you add a salary cost, please specify *who* this is for and *which* role this person plays in the project.

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.

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

Additional contributions for the project:
Funding/investments, both received and applied for, should 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 BII.

NNF 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. There can be no budgetary overlaps, and it must be clearly described how this proposed project is different from and/or coherent with the project already funded.
- If an identical or overlapping project proposal has been or will be submitted (prior to the grant notification of this call) to other funding institutions than NNF, it must be described clearly in 'supplementary information' for the budget. It must be noted to what extent the project and budget posts are overlapping. In the case of an applicant being successful in obtaining both

grants of overlapping project applications the grant may be annulled or reduced to the non-overlapping project parts and budget posts of the applications.

- If the applicant, post application submission, receives funding for the project or parts of the applied project from others, BII must be contacted as soon as possible.

3.4 MANDATORY UPLOADS

In this section, you must upload the following mandatory uploads (PDF only):

- Hosting letter. In this document, the host institution declares that the project can take place at the given institution during the project period.
- Short CVs of maximum 2 pages per person (applicant and key team members). If any co-applicants, these must upload CV under the tab co-applicant upload(s).
- Slide deck supporting the project description (see section 3.2). Maximum 30 slides.
- Letter of support from the Tech Transfer Office. This is to confirm support for the project, the proposed commercialisation plan and that access to enabling technologies will be given.

Failure to provide these may result in administrative rejection of the application. Any additional uploads (e.g. articles or patent applications) will be deleted.

For our due diligence process we will ask for a non-confidential slide deck to share with external experts. Please be prepared to provide this upon request but do not upload multiple slide decks in the application.

PREVIOUS AND CURRENT GRANTS FROM NNF

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.

About BioInnovation Institute

The BioInnovation Institute (BII) is an initiative of the Novo Nordisk Foundation, an independent Danish Foundation with corporate interests.

BII embraces every phase of a life-science start-up company and though we are based in Denmark, our aspirations are international.

BII offers entrepreneurially-minded researchers or anyone with a research-based idea help to bring interdisciplinary ideas to life and research to market. BII offers state-of-the-art facilities and various funding opportunities, as well as partnerships and programs with technical, scientific, and commercial experts.

Our focus areas are therapeutics, bioindustrials and medical technologies. We envision that strong collaborations, a passion for science, and an open mind will foster research-based innovation and viable start-ups, for the benefit of human welfare and society around the globe.