

**BIOINNOVATION
INSTITUTE INCUBATION
PROGRAM AND
CONVERTIBLE LOAN**

Information and guidelines for applicants

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Convertible loan information

Convertible loan capital:
Maximum DKK 10 million

Application form opens:
August 30, 2018

Application deadline:
September 27, 2018, 12 noon

Applicant notification:
December, 2018

Earliest start date:
January, 2019

Latest start date:
December, 2019

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1 BIOINNOVATION INSTITUTE INCUBATION PROGRAM AND CONVERTIBLE LOAN

1.1 PURPOSE

The BioInnovation Institute (BII) Incubation Program offers a business-building platform for biomedicine, medical technology and biotechnology companies in their early life where discoveries are refined into solutions and business plan is executed.

Purpose is to facilitate that innovative solutions are brought to market as products or services that can benefit human welfare and society.

1.2 ELIGIBILITY

- Applying companies for the BII Incubation Program must be represented by one or more individuals with an academic background at master's level or equivalent.
- An application for the BII Incubation program is a convertible loan request which can be submitted by established companies only, i.e. companies that are CVR registered in Denmark.
- One CVR registration equals one application, i.e. individual owners of the same company cannot submit numerous applications in parallel.
- Only a single convertible loan is permitted per company or activities related to the same project.
- Applying companies should have obtained technical proof of concept for their discovery and either own or have full license to the IPR.
- Eligibility also implies willingness and ability to relocate physically to the BII Incubator in Copenhagen where laboratories and open offices are provided.

LIMITATIONS AND QUARANTINE

The applying company can be engaged with a grant program from BII at the time of application, however is not eligible for application if the start time of the first pay-out of a convertible loan tranche overlaps with the duration of another BII program.

Simultaneous applications for more than one of BII's various programs are not accepted.

If a company submits the same (or a very similar) application in two consecutive application rounds without being issued a convertible loan, the company will be quarantined from applying for BII Incubation convertible loans for a year, except if the company changes to a very different character and focus.



IMPORTANT! The BioInnovation Institute has a physical presence in Copenhagen where incubator convertible loan recipients has to be physically located and where their main research activities must be conducted.

1.3 RESEARCH FIELDS

The BII Incubation Program facilitates the commercialization process of Danish anchored start-up companies that can bring a new product and/or service to market within the life science fields of biomedicine, medical technology and biotechnology.

The commercialization process should exit the start-up with attraction of commercial funding.

Non-scientific aspects, identified in the business plan, are equally supported by the BII Incubation program's convertible loans, e.g. fulfilling regulatory requirements, business processes or educational needs.

1.4 FUNDING

Each loan can be up to DKK 10 million paid in tranches and can run over a maximum period of 18 months.

Participation in the BII Incubation program is supported by convertible loans, i.e. loans that are issued unsecured, leaving the companies free from repayment in case their company fail to succeed. If the company is unable to generate a return, the loan will be converted into a donation.

The application for a convertible loan must be submitted with a detailed budget (Excel upload which details the high-level budget submitted in the system's budget section), linked to the company's scientific and/or commercial development milestones.

Convertible loans from BII can co-exist with other funding, however non-commercial investments only. Supplementary funding and descriptions of the parties associated with other funding agreement must be included in the budget and application.

The convertible loan can cover expenses such as e.g.:

- Salary for staff
- Research activities, e.g. testing and experiments, CROs
- Development of MVP, prototypes
- Publications
- Patent applications
- Costs related to the commercialization process, i.e. market analysis
- Non-scientific costs, among others accounting and business processes
- Expenses for administrative support*
- Bench fee**

* Administrative support, definition:

- 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.

** Bench fee, definition:

- Support for individual researchers for the coverage of direct expenses needed to conduct the research project applied for.
- 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.



IMPORTANT! Participation in the BII Incubation Program implies physical presence at BII's incubator in Copenhagen where laboratories and open offices are part of the program. It is expected that participating companies play an active role in peer-to-peer development and social activities.

1.5 LANGUAGE

The application must be in English.

1.6 APPLICATION PROCESS

Applications for the BII Incubation program are open twice a year.

Please read "Terms and conditions for BioInnovation Institute", that all funding recipients must comply with before submitting an application:

<https://bioinnovationinstitute.com/terms-and-conditions-for-bioinnovation-institute/>

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>

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

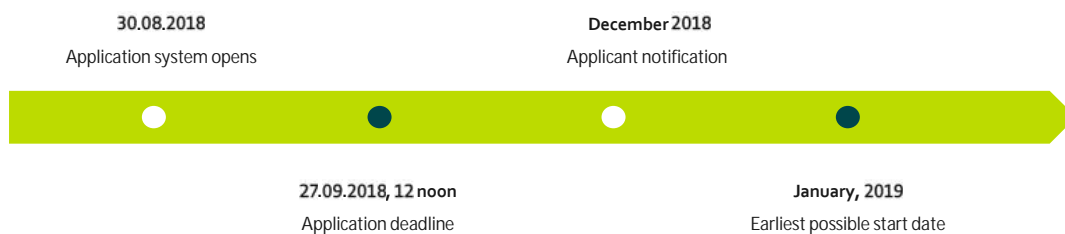
The BII Board of Directors (BoD) will evaluate the applications and base their assessment on the following criteria:

- The qualifications of the applying project team and their commitment and ability to further progress the project
- Significance and originality of the idea
- Commercial potential
- The IPR and legal situation for the research findings behind the project
- The suggested approach for further development



IMPORTANT! The BioInnovation Institute or the Novo Nordisk Foundation does not provide feedback in case the company is not selected for funding.

1.8 IMPORTANT DATES



1.9 LOCATION

Participation in BII's Incubation Program is carried out physically at BII's incubator which is located in Copenhagen (Ole Maaløes Vej 3). It is expected that loan recipients relocate to the incubator where open offices and laboratories are offered at a reasonable cost, to carry out their main activities.

Furthermore, it is expected that companies present at the incubator play an active role in peer-to-peer development and social activities.

1.10 SCIENTIFIC REPORTING

BII Incubator Program convertible loans recipients are required to report annually on their scientific activities through the online tool Researchfish.

Data from Researchfish is used as one of multiple sources to generate the Foundation's impact assessment.

Participants in the BII Incubator Program will be established in Researchfish by the Foundation. Further information on reporting requirements will be provided for the participating companies once selected.

1.11 FINANCIAL REPORTING

Throughout the BII Incubation program, the BII secretariat will assess whether the loan tranches have been spent in accordance with the budget information provided in the application and settled in the loan agreement.

Hence, financial and commercial milestones are assessed at the beginning and end of each paid loan tranche.

Possible changes to the overall budget can be submitted at any time during the BII Incubation program following agreement between the BII secretariat and the company.

Considerable discrepancies between provided budget and running budget must be evaluated by BII secretariat and participating company in collaboration and appropriate actions and mitigations must be undertaken.

1.12 IMPORTANT INFORMATION WHEN COMPLETING THE APPLICATION

Application form will open August 30, 2018, in the electronic system.

Information needed to complete the online form is mentioned below:

Personal information:

Name, email, phone, gender, nationality, residential country, date of birth, ORCID.

Company information:

CVR number

Companies with IPO is not in scope

Soft funding is recommended

No diluted funding

Educational information:

Highest degree attained, date of degree, institution.

Host institution:

Please select 'BiolInnovation Institute' as your host institution.

Administrating institution:

Please select 'BiolInnovation Institute' as your host institution.

Applicant information:

CV (max. 4,000 characters).

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.

Project description:

The BII Incubator Program application of maximum 10,000 characters (with the possibility to add supporting uploads in any format) must cover but is not limited to the following areas:

- ✓ Overview of the project team and their scientific and commercial competencies
- ✓ Demonstration of scientific excellence of research

- ✓ Business plan, including an overview of scientific/commercial milestones
- ✓ Budget for all activities expected to undertake during the BII Incubation Program. These can be among other CRO/CMO expenses, salaries, use of laboratories, testing, prototyping, market insight, travel, IT, legal registrations, patenting
- ✓ A draft vision for the company following the BII Incubation Program, i.e. what kind of external funding and additional maturity activities are expected for post incubation growth of the company

As part of the evaluation of incoming applications, companies that qualify as top candidates will receive an invitation for an interview session of app. 1-2 hours duration. Instructions for preparation and presentation at the interview will be provided for these top selected candidates only.

Project information:

Loan period (start and end date), project title, brief project description, lay project description, category choice, literature references, estimated time to market.

Previous and current grants/funding and applications:

If you within the last 5 years have received funding as an applicant or co-applicant, please provide the application number, project title and status of the project, and specify the relation to the current application. Likewise for pending applications.

IPR information:

List of published patent applications.

Competitor information:

List of nearest competitors/peers if known.

Customer traction:

List of potential customers/patients.

Budget:

It is important that each budget post is carefully described, and entered per budget-year (not per calendar year).

Timelines:

Description of key milestones and value infliction points in the project

2 THE NOVO NORDISK FOUNDATION APPLICATION SYSTEM - NORMA

2.1 REGISTRATION – ORGANISATIONAL APPLICANT FOR COMPANY APPLICATIONS

The BioInnovation Institute (BII) is a subsidiary of the Novo Nordisk Foundation (NNF) and hence the application for BII has to be submitted through the Novo Nordisk Foundation application system "NORMA".

An applying company must select a member of the company to be the main organizational applicant in NORMA.

Please see section 3 on how to get your company registered and ready for applications submission. Furthermore, you need to register an organizational applicant.

The novel company which applies for funding must be registered in NORMA before the company's main organizational applicant is able to prepare and submit the company application.

Please allow app. 2 work days for registration of a new company in the system, i.e. we recommend that you ensure a company registration early in the application process.

User registration and company applications will be further described in the below section 3.

NOTE! If the organizational applicant is already individually registered in the Novo Nordisk Foundation's application system from previous application rounds, you must contact BII for an adjustment of your profile and systems settings.

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.

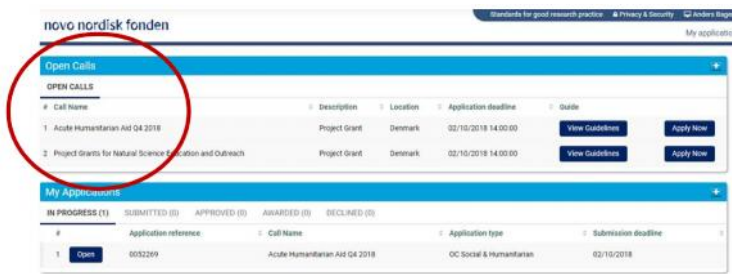
Once the application has been submitted, a confirmation of receipt will be sent to the e-mail address used for logging into the system. If you do not receive a confirmation of receipt, you should contact NNF as soon as possible using the contact details on page 3.

Confidentiality

All applicant and application information will be treated confidentially.

2.3 IDENTIFYING THE CORRECT OPEN CALL IN NORMA

Once you are registered as a new user in NORMA, you can initiate an application by identification of the call and funding you wish to apply for. Immediately when logged on, you can see the 'OPEN CALLS' section, which is located in the upper section of the screen.



In the 'OPEN CALLS' section, all currently available funding for organisations and companies from NNF are available. Select the relevant call to apply for.

NOTE! If the main organizational applicant is already individually registered in the Novo Nordisk Foundation's application system from previous application rounds, you must contact BII for an adjustment of your profile and systems settings – you may not be able to see calls for companies.

In case you are an existing user of NNF's application system, you can log into NORMA and enter 'My Applications' which is located beneath the 'OPEN CALLS' section. Here, 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.

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 funding 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.



IMPORTANT! For readability purposes, standard fonts and font size 11-12 must be used.

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'.
- If content of your budget row is not represented in the drop down, please use 'other'.
- 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.

3 PREPARE AND SUBMIT A COMPANY APPLICATION

3.1 COMPANY USER REGISTRATION

NORMA will open from the link at the Novo Nordisk Foundation's webpage or directly at: <http://norma.novonordiskfonden.dk/>.

First, you should submit a registration of your novel company.

novo nordisk fonden

As a company applicant, you need to register your novel company as well as a main applicant profile (the 'organisational applicant') that applies on behalf of the company.

Please allow app. 2 days for processing of the company registration.

Company registration must be done in advance of the profile registration, i.e. start with a submission of the company.

How to register your company in Norma.

novo nordisk fonden Applicant registration

①

As a company applicant, please initiate a registration of the novel company by clicking 'this link'.

Do not write anything in the form.

②

Your company must be added to the Norma system.

Choose 'click here' in order to fill in the form.

③

Submit the data of your company and submit form.

Please allow app. 2 days for processing of the company registration.

When the company is registered in the system, the organizational user application profile must be created

When your company is registered in the Norma system – remember to allow app. 2 days for processing – you need to create the 'organisational applicant' profile that submits the application on behalf of the applying company.

NOTE! If you already have a registered profile in the Novo Nordisk Foundation application system, please contact BII for a change of your profile in the system settings.

Organisational Applicant

Important
Please fill in the fields below.

* Organisation Name

If your organisation is not in the list above, please [click here](#) to register.

* Organisation branch/ department/ faculty

* First name

* Last name

* Email

You choose your company in the 'organisation name' field and fill in rest of the data.

For any new user registration, remember to select 'submit' at the end of the process: new users will receive an email with user name (your email address is identical with your user name) and password which you are requested to change at first log-on in NORMA

The email address registered for step 1 should be the work email of the main applicant. Later, this can be changed if needed by contacting the Novo Nordisk Foundation.

In the system, the main applicant's user profile is linked to the company application as 'main applicant'.



IMPORTANT!

It may take up to 2 working days to register a new company in NORMA. It is not possible to initiate a company application until the novel company has been registered in the system and the associated organizational applicant has been created.

3.2 ORGANISATION INFORMATION

Applicants must select their registered company as both applying and administrating organisation.

Please allow app. 2 work days following your submission of a company registration in the system before the company can be found in the drop down menu list of 'organisations'.

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 main focus is medical technology, pharma and biotechnology. 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.

