



BIO STUDIO PROGRAM

A LEADING LIFE SCIENCE COMPANY CREATION FACILITY

GRANT FUNDING FOR ENTREPRENEURIAL RESEARCH PROJECTS

Information and guidelines for applicants

Feb 2023

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BASIC INFORMATION

Funding and support:

- Research grant and support grant of up to DKK 7.86M (~EUR 1M) per year per project.
- Incubation at BII's co-working office and lab space in central Copenhagen.
- Scientific, IP and business development support and training opportunities at the BII.
- Access to BII's network of industrial, investment, business, and infrastructure partners.

Duration:

Project duration of up to 3 years.

Application:

Direct invitation from BII and/or via thematic call expression of interest.

Up to two annual assessments:

Approvals in June and December.

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Bio Studio Operations

1 THE BIO STUDIO

1.1 WHAT IS BII BIO STUDIO?

The Bio Studio program supports world-leading entrepreneurial Principal Investigators (PIs) who want to translate their innovative research ideas into new products and solutions for the benefit of people and society. Bio Studio is specifically designed to support innovative projects originating from universities, hospitals, and/or other research institutes. The PIs home institution maintains rights to all intellectual property (IP). As a commercial foundation with a non-profit objective, the BioInnovation Institute Foundation (BII) has no economic stake in any future spin-out company generated within the Bio Studio Program and does not take any royalties on the IP generated in the projects.

With the Bio Studio program, BII has the ambition of building and running the leading life science *company creation facility* in Europe. At full scale, Bio Studio will host 15-25 entrepreneurial PIs and will employ around 100 researchers and bio-entrepreneurs dedicated to establishing the next generation of life-science companies.

PIs will establish satellite groups at BII's facilities in Copenhagen where projects will be incubated for up to 3 years with the aim of creating viable companies capable of attracting significant commercial financing (seed or Series A). BII has created a unique interdisciplinary environment with the support necessary to reach this goal, including access to labs and office space, business development, and IP support. Additionally, BII will support developing and maturing the projects, recruiting team members, and preparing the teams for the creation of their company and subsequent fundraising. The project teams will have access to educational elements focussed on developing a broad range of business and entrepreneurial competencies. BII will also provide opportunities for participants to meet and interact with BII's global network of investors, industrial partners, alumni, and fellow entrepreneurs across our other programs.

The PI will be affiliated with BII as a consultant and the project will be directed by a commercial Entrepreneur in Residence (EIR) who will also act as day-to-day manager for the research team at BII. A typical Bio Studio team will consist of the PI, the EIR, and 3-5 researchers. The researchers and the EIR will be employed by BII and be primarily working at BII.

1.2 FOCUS AREAS

BII supports innovative life science projects developing new transformative solutions within human and planetary health. The specific focus areas are listed below. However, life science innovation projects outside of these themes will also be considered if they create significant impact.

Human Health	Planetary Health
<p>New biology revealing novel drug targets.</p> <p>Next wave modalities for improved treatment.</p> <p>Digital healthcare solutions.</p> <p>Advanced diagnostics enabling predictive medicine.</p> <p>Women's health:</p> <ul style="list-style-type: none"> • Female specific conditions • Conditions with high incidence/differential presentation in females • Fertility and reproductive health 	<p>Sustainable healthy foods and novel foods.</p> <p>Improving agricultural production, soil health, and water quality.</p>

1.3 PROGRAM CONTENT

On-boarding

Upon project approval (see Section 2. Application Process), BII will initiate the process of recruiting the project team in collaboration with the PI. Prior to project start, BII will work with the team to create a concise milestone plan and prepare the facilities for project execution, including access to the necessary equipment and infrastructure. The milestone plan describes the value inflection points in relation to key scientific, business development, and team milestones that you will need to execute during the time at BII.

Recruitment

BII will be responsible for employing the project team and will work in close collaboration with the PI to establish a team with the required competencies within e.g. R&D research, business development and project management. Upon company creation at the end of the project, BII can also support in recruitment of additional team members. Ideally, the EIR continues as CEO in the spin-out company, but this will be assessed once approaching a funding event.

BII Partnerships

All Bio Studio teams will be introduced to our partners and their services at an early stage of project initiation. The partners range from consultancies within IP, legal, taxes, and executive search to CROs and market analysis. The partners have been hand-picked to help boost your development plan and company creation. A full list of partners can be found [here](#).

BII community, knowledge sharing, and workshops

Being physically present at BII, your Bio Studio team will be part of a thriving ecosystem of fellow projects and start-ups in different phases of their journey. This is an opportunity to meet and learn from like-minded people. Activities the team will participate in include:

- **EIR meetings:** EIRs from the different Bio Studio projects meet up to exchange experiences and discuss relevant topics.
- **Workshops:** Teams will have access to workshops on various topics depending on project needs, e.g. introduction to IP, developing entrepreneurial competencies, team building, pitch preparation, fundraising. These workshops will either be specific for Bio Studio teams or involve relevant modules from the content developed for the other BII Programs; Venture Lab and Venture House.




- **Preparing for fundraising:** During the program, the Bio Studio teams will also be supported by several initiatives to help prepare for fundraising (e.g. developing strategies for soft funding acquisition, VC bootcamp to get feedback on pitch decks, and pitch sessions with relevant VCs from the BII network).

Project management and governance

The enrolled projects will be supported by dedicated BII Scientific Project Managers who together with the EIR will help to guide business and project development throughout the 3-year period at the BII. Project progression will be closely monitored at regular progress meetings. In case the project is not successful in reaching critical milestones, the project will either pivot its path or be discontinued at annual review if a continuation is not viable.

Interdisciplinary skills are needed for these translational projects and for all Bio Studio projects, a Project Board will be established with internal and external expertise based on the project-specific needs for strategic guidance. Meetings will be held 2-4 times a year focusing on key aspects for the project to obtain a successful company creation within the 3-year timeframe.

Bio Studio Program content during the project and key outcomes

Science 	Business 	Team 
<p>During the project:</p> <ul style="list-style-type: none"> • Project development and management support • Laboratory and office facilities • Infrastructure and partnering support <p>Key outcome:</p> <ul style="list-style-type: none"> • Solid data package demonstrating proof-of-concept in relevant models • Safety data in place (if relevant) • Development plan and budget established to reach clinical/industrial proof of concept 	<p>During the project:</p> <ul style="list-style-type: none"> • Access to VC and other relevant networks • Workshops & courses: Business development, IP, pitch training, strategy, & fundraising <p>Key outcome:</p> <ul style="list-style-type: none"> • Tested target product profile / minimal viable product and uniqueness • Unmet need/impact clearly defined • IP and regulatory strategy in place and freedom-to-operate analysis completed • Strategy and business plan for supporting the next 2-3 years 	<p>During the project:</p> <ul style="list-style-type: none"> • Recruitment support: Team members employed at BII on Bio Studio specific contracts • Workshops & courses: entrepreneurial competencies, team development <p>Key outcome:</p> <ul style="list-style-type: none"> • Cohesive project team • Capable management team in place for spin-out • Advisory/Project Board in place

1.4 TERMS

Presence at the BII

The Bio Studio project team will be employed by BII and thereby benefit from the entrepreneurial ecosystem and cohort support delivered by BII. As such, relevant project activities can take place at the host institution of the PI if the necessary infrastructure capabilities are not available at BII or via contract research organizations. The PIs themselves are not expected to reside at BII as the daily management of Bio Studio projects are carried out by a dedicated EIR recruited for the specific project. The PI is expected to be an active part of the BII community by joining the strategic Project Board meetings, annual Bio Studio PI seminars and other relevant Bio Studio meetings and events.

Intellectual Property Rights (IPR)

BII does not claim ownership of any IP generated prior to or in the Bio Studio project and the assignment of IP will be based on the rules of IP ownership of the PIs home institution. In cases where the PIs home institution owns the IP from general principles of law, BII will enter into a collaboration agreement with the institution to regulate the handling of relevant IP generated prior to (Background IP) or during the Bio Studio project (Foreground IP). The purpose of the collaboration agreement is to ensure that a future spin-out company is guaranteed a license to all relevant Background and Foreground IP on pre-negotiated market terms.

If a collaboration agreement is not already in place with the PI's home institution, an agreement will be established after the project has been approved for funding and is required to be in place before the project starts.

LIMITATIONS

Bio Studio can only support pre-commercial projects with no commercial investments or IP ownership. Projects that have received commercial investments, certain types of loans or are supported by corporates/investors/commercial foundations are disqualified from applying. Bio Studio grants will also not be given to projects that overlap with work done at a spin-out company that the PI has founded. The purpose of the Bio Studio grants is to establish new spin-outs after the grant period and not to support existing companies.

1.5 ELIGIBILITY CRITERIA

The projects are expected to meet the following criteria to be considered for the Bio Studio program:

Geographical

- Independent PIs associated with universities, hospitals or other research institutions around the world are eligible to apply.

PI

- Strong academic track record considering the career stage of the PI.
- Proven experience of leading an independent research group (at least 3 years as an independent PI).
- Entrepreneurial mindset: preferably with demonstrated experience of translating research (i.e. Applicant has (co-)founded spin-out companies, significant prior industrial leadership experience, or other relevant experience of translating research into products or solutions).

Scientific and technological readiness

- The scientific rationale and documentation validate the idea. Must be based on internal indicative data supporting the rationale.

Commercial potential

- The proposed solution addresses a significant current or future market need.

Team

- Indication that at least one scientist key to the project can transfer from the PIs group to BII.

IP

- No IP is required for initiating a Bio Studio project.
- Indication that any IP generated prior to project start (Background IP) and owned by home institution can be licensed to future spin-out company on market terms as described in Section 1.4. Terms.

1.6 PROJECT FUNDING

Bio Studio project funding is designed to allow PIs to establish a satellite group where the scientific team based at BII in Copenhagen work towards formation of the new spin-out company within the 3-year grant. By conclusion of the first year, it is expected that all or most activities are located at BII in Copenhagen. Bio Studio projects are expected to run for up to 3 years and the funding is awarded in sequential 1-year tranches. BII provides an annual grant consisting of assets with a total market value of up to DKK 7.86M. When submitting a Bio Studio proposal the applicant is asked to prepare a project budget (Project Budget)^[1] of up to DKK 5M per year, which may include a cash out amount for activities that must operate from the home institution. Annual extension of the grant is approved by the BII Board based on progression of the milestone plan.

Expenses that must be included in the Project Budget:

- Salaries for EIR and research staff
- Research activities at BII including project-specific consumables (a list of provided consumables is supplied to applicant with the budget template)
- Staff competencies development activities (e.g. BII-CBS Summer School, workshops, VC bootcamp, attendance at conferences or relevant scientific events)
- Travel for PI to participate in BII events (where relevant)
- Human resource related costs (e.g. team and culture building, mobility and recruitment)
- Depreciation related to project-specific equipment purchased by BII (if relevant)
- Business development (e.g. assistance for soft funding applications, market reports, and database access)
- Special legal fees (e.g. establishment of MTA)

Expenses that can be included in the Project Budget:

- Research activities at CROs or university core facilities including consumables, testing, and experiments that strengthen the commercial potential of the project idea/invention
- Clinical research costs at hospitals needed to collect relevant samples and data to strengthen the commercial potential of the project idea/invention

^[1] VAT of 25% must be included in all relevant costs of budget.

- Development of MVPs, prototypes, and therapeutic modalities (small molecules, biologics, cell therapies)
- Development of regulatory strategy and compliance
- Establishment and maintenance of a data room
- Travel costs of team members and scientific advisors where appropriate (e.g. for training and skill-sharing)
- IPR-associated costs may also be covered¹
- Administrative/Overhead fee to a maximum 5%

Expenses that are not covered by the Bio Studio grant:

- Equipment placed at PI home institution
- Company establishment costs

In addition to the Project Budget, the grant includes the following assets:

- IP costs
- PI contribution
- Rent
- IT (base IT package)

1.7 BEING PART OF THE BII COMMUNITY

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

2 APPLICATION PROCESS

2.1 EXPRESSION OF INTEREST

The Bio Studio Program is a strategic effort where we are continuously and actively sourcing projects that match the themes within BII's Bio Studio focus areas (see table above). We regularly run thematic EoI's as published on the BII website in strategic areas of interest. However, we are keen to hear from entrepreneurial PIs working within our thematic areas. If you meet the Bio Studio eligibility criteria (see above) and have a translational project in mind, please send your Expression of Interest (EoI) via the online form at our website for this purpose.

The EoI includes:

- Name and country of the research institution
- Website (URL) of the research group
- Brief statement (max ½ page) answering following questions:
 - What is the problem you want to solve and how is this an unmet need?

¹ Costs relating to maintaining Background IP may be covered depending on the collaboration agreement between BII and host institution.

- What is your solution to the problem?
- How large is the market for your solution and how do you envision entering the market?

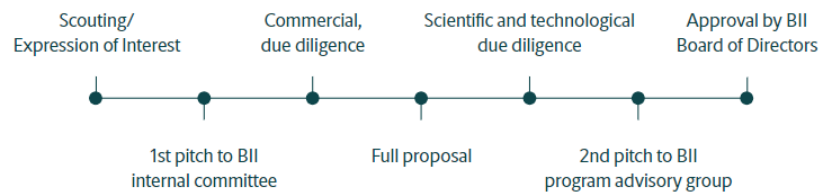
For your EoI, you must also submit a:

- CV² (max 2 pages) detailing relevant academic and entrepreneurial experience (employment history, recent publication track record, filed/granted patents, description of (co-)founded companies).
- Non-confidential slide deck (max 5 slides) describing the envisioned project including a) the problem you want to solve, b) the proposed solution, its commercial potential, and advantages over existing solutions, c) outline of the 3-year project plan. It is mandatory to use the [BII template](#) that can be downloaded from our website.

We will use this information to assess the fit to the Bio Studio program and will contact you about if and how to proceed with the application process within 3 weeks of receiving the EoI.

2.2 EVALUATION

BII recruits projects and evaluates the invited proposals in multiple steps. The overall assessment stages are shown below. Internal alignment meetings are held at each stage below to progress the application.



During the initial EoI or scouting process, BII personnel will work with the PI to determine a suitable translational plan, which may involve several meetings. Hereafter, the evaluation process will consist of two main stages:

Stage 1: Official pitch to an internal BII committee consisting of the BII CXO team and representatives from the BII Science & Tech, Business Development, and Innovation departments. If the internal BII committee decides to proceed, BII will perform due diligence on the project. Subsequently, the BII committee decides if the Applicant should be invited to submit a full proposal.

Stage 2: An application with a full proposal and budget. Further due diligence is performed. The Applicant will be invited to pitch for BII's Program Advisory Groups, which will provide recommendations for BII. The Program Advisory Groups consist of experts and VCs working within human health and planetary health. Finally, the BII Board of Directors makes the final decision based on recommendations from the Program Advisory Group and BII.

The process from the 1st official Pitch to project approval takes approximately 9 months. Note that some of the process steps can occur simultaneously (e.g. engagement with the universities/TTOs and commercial, market, and competitive due diligence). If approved the anticipated time from Board approval to project

² Please do not include any personal information such as home address, phone number, social security number etc.

start is ca. 6 months for Danish projects and 6-9 months for international projects³. Throughout this process the PI and Science Team will work together to mature the project plan.

2.3 EVALUATION CRITERIA

The evaluation will be based on the following criteria:

Scientific novelty and ambition

- The idea is original and has the potential to address societal or health challenges that have a large impact on people/patients and/or society.
- The proposed solution is based on transformative science and/or technologies.
- The proposed solution addresses a hard problem that requires research work before commercialization (i.e. not purely product development).

Commercial potential

- The project addresses an unmet need with significant market potential.
- The proposed solution idea is different from competing products on the market or in development (e.g. clinical trials).
- The proposed commercial development plan is realistic.

Team

- The PI has the entrepreneurial background and the scientific skills and qualifications to drive the project successfully.
- The Team has the necessary competencies to execute the proposed project plan.
- The hiring plan adds the missing competencies (e.g. commercial or scientific/technical) to the project Team.

Fundability

- The proposed project has the potential to spin out a viable company capable of attracting significant commercial financing (seed or Series A) by the end of the 3-year program.

2.4 PROPOSAL, BUDGET, AND PROGRAM ADVISORY GROUP PITCH

If an Applicant is invited to submit a full proposal, the proposal and budget templates will be provided by BII. Additionally, a letter of support from The Applicants home institution is required. The Applicant will have one month to complete the proposal, which will constitute of a proposal of 10-12 pages covering the sections below:

- **Objective:** a description of the project objective and the specific research aims
- **Team:** detailing the envisioned project team, including a description of profiles of the people that you plan to hire for the team.
- **Collaborators:** if any, specifying their key competencies and contribution.
- **Impact and value proposition:** detailing the unmet need and the specific problem you aim to solve

³ Danish projects are expected to begin faster where a collaboration agreement is already in place between BII and the PIs host institution. This time is to allow for drafting and finalizing of the collaboration agreement (where required), relocation for key team members, hiring new team members, and acquisition of any key equipment required for initiating the project.

- **State of the art:** putting the project idea in the context of the current state of the art.
- **Development plan:** specifying the scientific development plan, business development plan, IP, and funding activities that must be executed during the project (a Gantt chart must be included).
- **Milestone plan:** listing the key scientific and business deliverables and measurable milestones associated with these.
- **Third-party IP:** specifying if there is IP owned or controlled by any third party, or co-owned or co-controlled by any third party, to which the project needs access.
- **Background technology (IP):** specifying if there exists any Background Technology which will be used as part of the Bio Studio project.
- **Envisioned start date**
- **References**

A budget⁴ template, which is an Excel sheet consisting of:

- **Salaries of staff:** team members who will be hired during the 3-year project timeline.
- **Expenses:** for equipment (including large and small project-specific equipment, depreciation, special IT), consumables, business development, team and culture building, travel for PI and staff, and outsourced experiments or manufacturing costs.
- **Partner contribution:** required only if the Collaborating partner is providing additional financial support on top of the BII financing.

And a letter of support from the home institution acknowledging their support for the application. Please note an email from the department head or other relevant person is sufficient.

After submission, the proposal will be sent in peer-review for assessment by at least 3 academic experts and scientific due diligence. Following scientific and commercial due diligence and peer-review, applicants will then be invited to pitch for the Program Advisory Group relevant for their specific proposal. The pitch should be no longer than 15 min presenting the project team, scientific excellence, and clear business potential and will be followed by 20 min Q&As. The pitch must follow the template provided by BII for this purpose.

2.5 CONFIDENTIALITY AND DATA PRIVACY

We are committed to treating all applicant information confidentially. Our commercial due diligence partners, academic peer-reviewers and Program Advisory Groups have all signed confidentiality agreements, protecting your information and are instructed to destroy or return all documentation after the review period is completed. Program Advisory Group members and peer-reviewers will declare a conflict of interest, if they work on/with a similar project as proposed by Applicant or have any conflicting relations to the Applicant (i.e. collaborator, close colleague, etc).

Any personal data we receive as part of your submission (name, e-mail, and CV information) will be treated as confidential information and will solely be processed for the purpose of assessing your application for the Bio Studio. We will process your information based on our legitimate interest⁵ in being able to initiate scouting discussions with eligible researchers for the Bio Studio.

⁴ As described in Section 1.6.

⁵ General Data Protection Regulation (GDPR) Article 6 (1) (f).

We may share your personal data with external due diligence partners, academic peer-reviewers, and Program Advisory Groups. When disclosure of your personal data involves transfer outside the EEA, such transfer will be based on the Commission's standard contractual clauses (as amended from time to time). You may request a copy of the clauses by reaching out to persondatanii@novo.dk.

If your application is successful and you are eligible for a grant or loan under the Bio Studio, we will process your personal data in accordance with our [general privacy notice](#).

If we decide not to proceed with your project, we will delete your application after 2 years following this decision.

You can request access to the personal data we process about you and request correction or deletion of such data. You may also object to the processing of your personal information or request data portability. You can make a request by forwarding it to persondatanii@novo.dk.

You also have a right to lodge a complaint with the Danish Data Protection Agency (Datatilsynet).

INFORMATION TO NOT PROVIDE

Although BII and our partners work under strict confidentiality, we advise you not to share the following in the initial pitch:

- Strain sequences
- Chemical structures
- Amino acid sequences
- Any other chemical/biological information that identifies your product

If your project is shortlisted for further due diligence, we might ask you to share this information with a very limited number of people under a specific CDA.

About BioInnovation Institute Foundation

The BioInnovation Institute Foundation (BII) is an international commercial foundation with a non-profit objective supported by the Novo Nordisk Foundation. BII operates an incubator to accelerate world-class life science innovation that drives development of new solutions by early life science start-ups for the benefit of people and society.

BII, located in Copenhagen, Denmark, offers start-ups and early-stage projects within Human Health (health tech, therapeutics, women's health) and Planetary Health: state-of-the-art labs, vibrant office facilities, business development, start-up business incubation, access to high-level mentoring, and international networks plus unique funding opportunities of up to EUR 1.3M per start-up and EUR 2.6M per research project.

Since the inauguration of BII in November 2018, BII has awarded more than 50 million EUR to 70 high-growth start-up companies. Read more on www.bioinnovationinstitute.com

