

BIO STUDIO

GRANT FUNDING FOR ENTREPRENEURIAL RESEARCH PROJECTS



Information & Guidelines for Applicants

August 2024

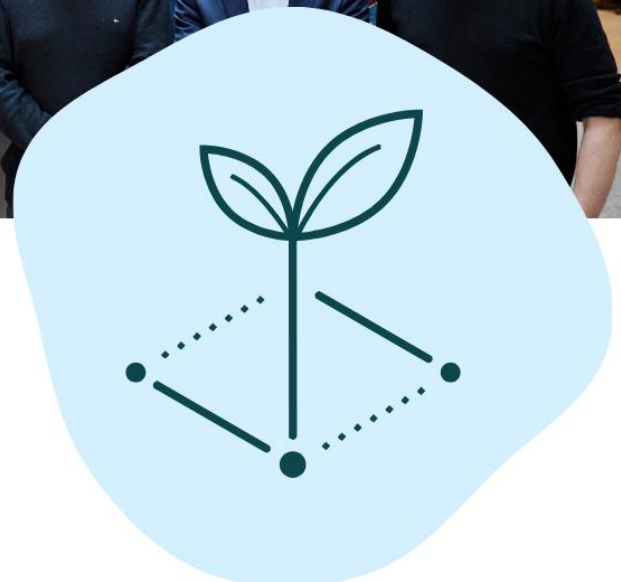


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BASIC INFORMATION

Funding and support:

- Project 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 knowledge and network of industrial, investment, business, and infrastructure partners.

Duration:

Project duration of up to 3 years.

Application deadline:

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

Up to two annual assessments:

Approval in June and December

Contacts

Project sourcing

Louise S. Clemmensen
Director, Science
Strategy
lcl@bii.dk
+45 9356 5574

Women's Health Specific Projects

Angela Ibler
Senior Associate,
Women's Health
aib@bii.dk
+45 4172 7917

Grant Manager / Administration

Iben Nikilajsen
Academic Relations
Manager
ini@bii.dk
+45 2062 3292

Bio Studio Operations

Shivani Joshi
Senior Associate,
Innovation
sjo@bii.dk
+45 2234 7397

1 THE BIO STUDIO PROGRAM

1.1 WHAT IS BIO STUDIO?

The Bio Studio program supports a world-leading entrepreneurial Principal Investigator (PI) in translating her/his 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 PI will remain at the home institution and the PI's 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 projects by 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 soft funding or 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 with 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 led by an Entrepreneur in Residence (EIR) who will be the 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 are expected to be primarily working at BII.

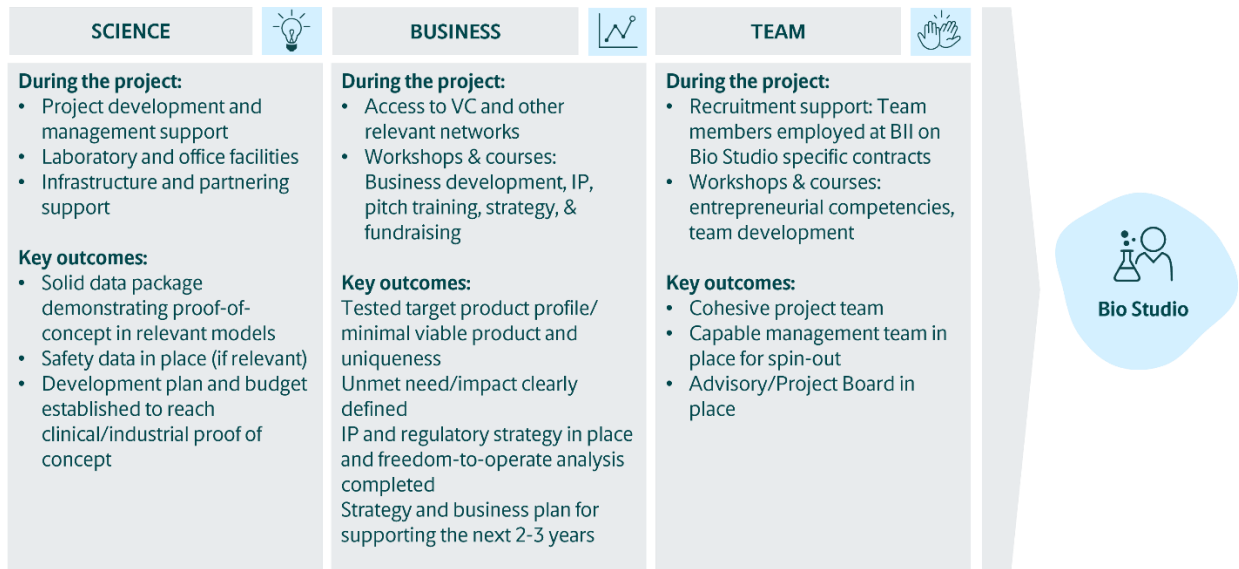
1.2 FOCUS AREAS

BII supports innovative life science projects developing new transformative solutions within human and planetary health. In Human Health we strive to deliver meaningful therapeutic and health tech solutions that improve health outcomes for people worldwide. In Planetary Health, we aim to support startups that develop innovative solutions to tackle the world's most pressing environmental challenges. 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.

<i>Specific focus areas of the Bio Studio Program</i>	
Human Health	Planetary Health
Oncology Immunology and inflammation Metabolic Diseases Infectious Diseases Neurological Diseases	Food & Beverages Agriculture Biomaterials & Chemicals Carbon Capture & Energy

<p>Women's health¹:</p> <ul style="list-style-type: none"> • Female specific conditions • Conditions with high incidence/differential presentation in females • Fertility and reproductive health 	
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1.3 PROGRAM CONTENT



Onboarding

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 your time at BII.

Recruitment

BII will be responsible for employing the project team and will work in close collaboration with the PI and EIR to establish a team with the required competencies within e.g. R&D research, product development, business development and project management. Preferably, the EIR continues as CEO in the spin-out company, but this will be assessed once a funding event approaches.

¹ Certain areas within women's health are jointly supported by BII and Ferring Pharmaceuticals through the Reproductive Medicine and Maternal Health Track – please read more [here](#). The areas within this track are: 1) Reproductive medicine related to the treatment of female infertility to increase the success rates of procedural based treatment (IVF, IVM, ICSI), therapeutics/non-therapeutics to treat the underlying causes of infertility (including implantation failure or endometrial receptivity), and male infertility; 2) PCOS or endometriosis; 3) Pregnancy related complications preeclampsia or pre-term birth. All areas can include therapeutics, diagnostics, or device solutions. Under this track, Ferring will participate closely in the due diligence process. Like other due diligence partners, they have signed a confidentiality agreement protecting your information and will be asked to declare any conflicts of interest before reviewing confidential information. For successful applicants in this track, the Bio Studio grant is provided on BII standard terms and conditions. Ferring will not have formal rights to a future start-up or the Bio Studio project's IP.

BII Collaborations

All Bio Studio teams will have access to our Collaborator network and their services from project initiation. The Collaborators range from consultancies within IP, legal, tax, and recruitment to Contract Research Organizations and market analysis. The partners have been hand-picked to help boost your development plan and company creation.

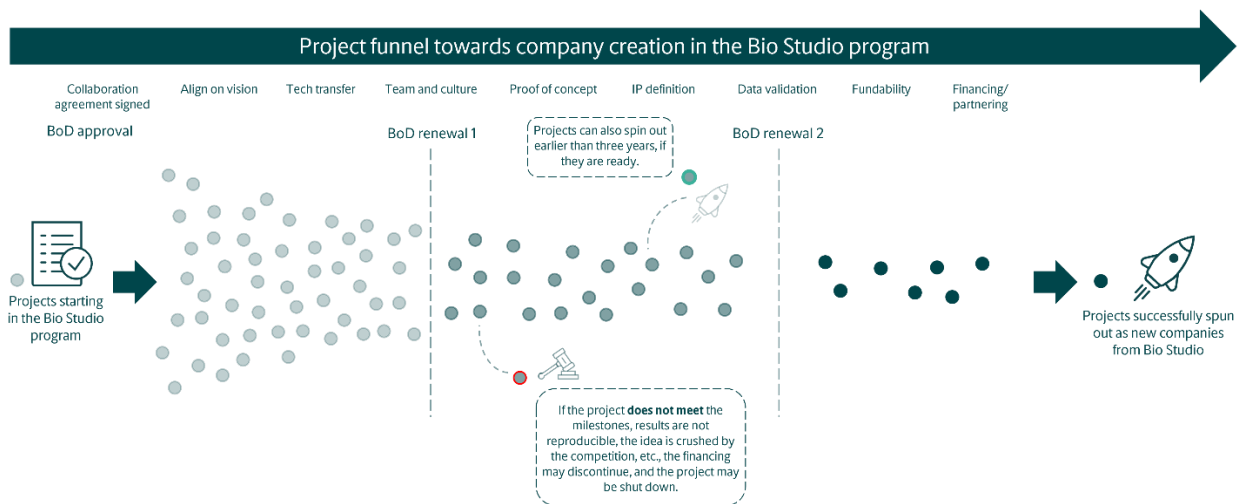
BII community, knowledge sharing, and workshops

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 and share experiences. 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, portfolio acceleration and governance

The enrolled projects will be supported by dedicated BII Anchors who work closely with EIRs and Project Teams to guide project, product and business development throughout the 3-year period at the BII. Project progression will be closely monitored at regular progress meetings as well as project board and bi-annual review meetings. During the first year the PI and team will also align on the cap table for the prospective company. If the project is unsuccessful in reaching critical milestones, it 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. Project Board 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.



1.4 TERMS

Presence at 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 PI him/herself is 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 during the Bio Studio project and the assignment of IP will be based on the rules of IP ownership of the PI's home institution. In cases where the PI's 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. To facilitate this process, it is advised that the PI engage with the host institution Tech Transfer office early in the project phase.

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

- An independent PI associated with universities, hospitals or other research institutions around the world is eligible to apply.

PI

- Strong academic track record considering the career stage of the PI.
- Professors and Associate Professors or equivalent with proven experience of at least 3 years of leading an independent research group.
- Entrepreneurial mindset: preferably with demonstrated experience of translating research (i.e. the applicant has (co-)founded spin-out companies, significant prior industrial leadership experience, or other relevant experience of translating research into products or solutions).
- Each Bio Studio project can be directed by only one main PI (the applicant).

Science and technology

- The scientific rationale and documentation validate the idea. The translatability must be evident and documented through internal indicative data in a relevant model that is accepted in the field.
- The scientific outcome solves a huge challenge with potential for creating high impact.

- Preferably based on platform technologies.
- The science and technology must be transferable as the majority of R&D must be executed at BII.
- A collaborating PI can be included in the project if this is critical to reach the project goals. In such case, a letter of support from such collaborator and their Tech Transfer Office must be included in the full proposal, confirming the support for the collaborating PI to participate in the project and acceptance of the terms described in Section 1.4 regarding IP. Further note that the collaborator is not a co-applicant, and that including a collaborator in the project will result in a more complex collaboration agreement.

Commercial potential

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

Team

- Indication that at least one scientist (not a PhD student) key to the project can transfer from the PI's group to BII.

IP

- No IP is required for initiating a Bio Studio project.
- Prior to submitting a full proposal, the PI must agree with the Tech Transfer Office and other relevant parties within the host institution that any IP generated prior to project start (Background IP) and owned by home institution can be used for the project and licensed to a 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 the PI 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 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)
- 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

- 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 covered²
- Administrative/Overhead fee to a maximum 5% (only for a cash out part of the grant, if any).

Expenses that are not covered by the Bio Studio grant:

- Equipment placed at the PI's home institution and equipment with a cost above DKK 100.000, which requires approval of the BII CTO
- Company establishment costs
- Salary for the PI (a PI consultancy fee is included in the grant)
- Salary for PhD students.

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

- IP costs
- PI consultancy fee up to DKK 100.000 per project year
- Rent at BII
- Standard BII IT package (laptop, monitor, mouse, keyboard, phone and Office 365).

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

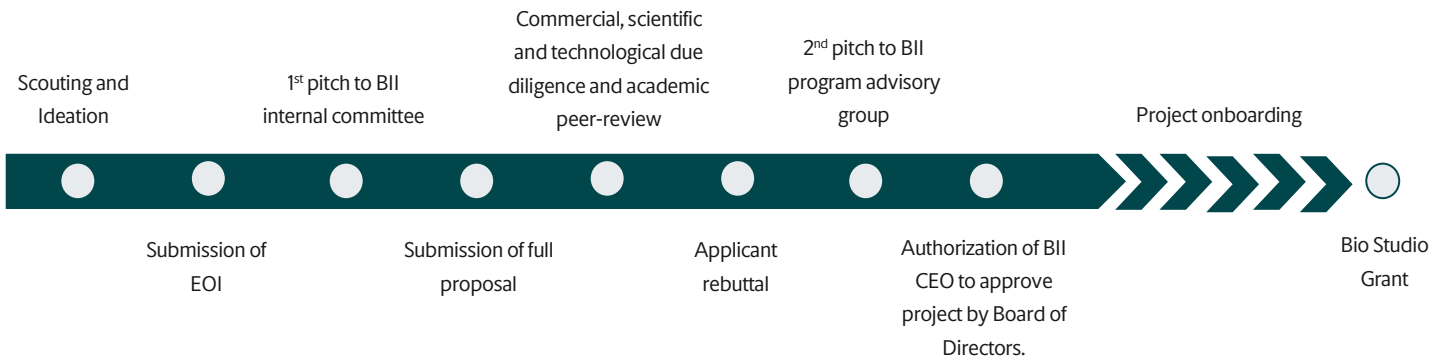
2.1 SCOUTING AND IDEATION

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 calls 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 contact our Science Team; Louise Clemmensen (lcl@bii.dk), Taylor Cooney (tco@bii.dk), or for projects within Women's Health Johanna Roostalu (jro@bii.dk). We will assess your project idea and the fit to the Bio Studio program and will contact you about if and how to proceed with the application process. If we would like to proceed with your project, you will be invited to submit a short Expression of Interest (EOI).

² Costs relating to maintaining Background IP may be covered depending on the collaboration agreement between BII and host institution.

2.2 EVALUATION

BII recruits projects and evaluates the invited proposals in a 2-stage application process. The overall assessment stages are shown below. Internal alignment meetings are held at each stage below to progress the application. During all stages of the application process, the applicant will work closely with BII staff.



Assessment stages for Bio Studio applications

During the initial scouting and ideation 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: EOI. Upon successful initial discussions of a translational project between the PI and the BII contact person, the applicant will be invited to submit a short EOI. Upon positive outcome of the evaluation of this EOI the applicant will be invited for an 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, the applicant will be invited to submit a full proposal. During the proposal phase the PI will be asked to take a personality test and an interview with People & Organization at BII. This is being done to ensure that the PI understands the values at BII and the purpose of the Bio Studio program. During this phase there will also be budget and equipment meetings with designated BII staff.

Stage 2: After the full proposal and budget has been submitted, full commercial, scientific and technological due diligence will be performed. Following the due diligence process the applicant will receive feedback and based on this submit a rebuttal. 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. Based on the recommendations from the Program Advisory Group, the BII Board of Directors makes the final decision on authorizing the BII CEO to approve the project.

The process from the Scouting and ideation phase to project approval takes approximately 7-8 months. If approved the anticipated time from Board approval to project start is approximately 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. A Bio Studio grant will not be formalized until the grant letter has been issued and signed subsequent to successful completion of a collaboration agreement and validation of both team and technology transfer.

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.

2.3 EVALUATION CRITERIA

The evaluation of both the expression of interest and the full proposal 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) or soft funding by the end of the 3-year program

2.4 EOI, PROPOSAL, BUDGET, AND PROGRAM ADVISORY GROUP PITCH

Upon successful initial discussions of a translational project between the PI and the BII contact person, the applicant will be invited to submit a short EOI. The EOI is a short 2-page application format covering:

- **Impact and value proposition:** detailing the unmet need and the specific problem you aim to solve.
- **State of the art and background data:** putting the project idea in the context of the current state of the art as well as describing the scientific background and data supporting your project idea.
- **Business Model & Market:** Explaining your intended business model and the potential market for your solution.
- **Team:** Describing the envisioned project team.
- **Project Plan:** What are key development activities (science, IP, business development) and milestones for the proposed 3-year Bio Studio project.

If an applicant is invited to submit a full proposal, the proposal and budget templates will be provided by BII. Additionally, letters of support from The Applicant's home institution and Tech Transfer Office are required. The Applicant will have 6 weeks 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. Please justify if a team member is not 100% based at BII or 100% allocated to the project.
- **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.
- **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 in Excel format, 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, special IT), consumables, business development, team and culture building, travel for PI and staff, and outsourced experiments or manufacturing costs. Please see list of equipment available at BII here: www.bii.dk/lab/
- **Third party contribution:** required only if the project has received co-financing from the PI's host institution or funding from other sources. Please note that BII cannot fund activities that have already been financed by other means (i.e. double funding of activities).
- Letters of support from the PI's home institution acknowledging the support for the application must be provided: 1) from the Department head acknowledging that the PI can engage in project, and if relevant, can use host institution infrastructure as outlined in the Proposal, and 2) from the Tech Transfer Office of the PI's home institution declaring if and what Background IP is available for the project. If the project involves a collaborator, the Letter of Support from the host institution's Tech Transfer Office should also acknowledge the collaboration and suggest how to handle IP generated during the project. Furthermore, a letter of support from such collaborator and their Tech Transfer Office must also be included. If the project relies on data/samples etc. the access to these must be documented. Access to clinical samples should be documented by a support letter from the collaborator with the samples.

After submission, the proposal will be sent in peer-review for assessment by at least 3 academic experts and commercial, technological and scientific due diligence. Following the peer review and due diligence the applicant will receive feedback from this evaluation and submit a rebuttal addressing the key feedback. After this, the applicant will 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.

⁴ As described in Section 1.6.

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.

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 persondatabii@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 persondatabii@novo.dk.

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

DO NOT PROVIDE THE FOLLOWING INFORMATION

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.

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

About BioInnovation Institute Foundation

At BioInnovation Institute (BII), we accelerate world-class life science start-up innovation to benefit people and society. As a non-profit institute, BII operates the company creation programs, Bio Studio, Venture Lab and Venture House, to support life science start-ups with knowledge, network, infrastructure and funding of up to 3M EUR per project and 1,8 M EUR per start-up. With our expertise, network, funding, and infrastructure, we empower startups to succeed and believe in the transformative power of life science innovation.

