BIO STUDIO

COMPANY CREATION PROGRAM FOR ENTREPRENEURIAL ACADEMIC RESEARCHERS









for Applicants

BIO STUDIO AT A GLANCE

BII's company creation program, Bio Studio, supports entrepreneurial academic group leaders in translating their science into innovative products and solutions.

Program overview:

- 3-year bespoke acceleration program to mature the project and prepare for spinning out.
- Each project is led by an Entrepreneur in Residence (EiR) with the Principal Investigator (PI) acting as a scientific consultant, providing input on the scientific direction.
- Projects are incubated at BIIs facilities in Copenhagen and are supported by BIIs infrastructure, including laboratory, office space, and a standard IT package and IT support.
- Scientific, IP, and business development support and training opportunities at BII.
- Access to BII's knowledge and network of industrial, investment, business, and infrastructure partners.
- Project grant of up to DKK 5.35m per year (EUR ~0.72m). Issued as an in-kind grant in Year 1 and 2 and as a convertible loan note in Year 3.
- Projects are strategically selected based on challenge call and scouting within focus areas.

Company creation timeline:

Each Bio Studio project is incubated at BII for a period of up to 3 years, with the aim of spinning out as a company in Year 3. In instances where projects achieve specific milestones ahead of schedule, spinning out is also possible during Year 2.

Application deadline:

Two thematic challenge calls per year in spring and autumn. See our website (<u>www.bii.dk/programs/bio-studio</u>) for exact application deadlines and scope for upcoming calls.

Contact:

For all inquiries regarding the Bio Studio program content, application and evaluation process, open calls and challenges, etc., please contact <u>BioStudioProgram@bii.dk</u>.



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1 THE BIO STUDIO PROGRAM

1.1 WHAT IS BIO STUDIO?

Bio Studio is designed to support world-leading entrepreneurial PIs in translating their science into innovative products and solutions. Projects joining Bio Studio will receive funding to establish a team that will reside at BII and get access to BII's infrastructure, including state-of-the-art laboratory facilities, knowhow and network. Bio Studio Projects will take part in a vibrant entrepreneurial community where they work alongside like-minded peers.

An EiR serves as the project leader and oversees project development, while the PI remains at their home institution, which retains all intellectual property (IP) rights generated during the project. A dedicated BII 'anchor' will guide projects through their progression towards company creation.

1.2 SCOPE AND BII CHALLENGE CALLS

BII supports innovative life science projects developing new transformative solutions for the benefit of planetary and human health. Bio Studio projects are sourced within strategic focus areas within **Human Health** (including Cardiometabolic Diseases, Infectious Diseases, Brain Health, Women's Health, and Cell and Gene Therapy), **Planetary Health** (Biosolutions and Power2X), and **Societal Resilience** (Al and Quantum).

Twice a year, BII will launch thematic Challenge calls within one selected priority area with unmet need and high innovation potential. BII Challenges are developed together with industry, business and scientific experts to scope problems requiring bold solutions based on scientific excellence. Find our latest BII Challenge call on the <u>BII website</u> and reach out to <u>BioStudioProgram@bii.dk</u> if you would like to hear more or discuss a project idea.

1.3 BIO STUDIO CONTENT

Once part of Bio Studio, projects gain access to an extensive support system assisting in all aspects of company creation through our bespoke acceleration program (Figure 1). Bll assists with scientific, as well as operational and business developmental aspects during the 3-year incubation period, building the optimal foundation for project maturation to a successful spin-out company. Bio Studio projects will be supported by a tailored program to develop entrepreneurial and commercial competencies of the team and will be guided by a dedicated Bll Anchor.

PROJECT FUNDING

The funding provided through Bio Studio consists of up to DKK 5.35m (EUR ~0.72m) per year for up to 3 years subjected to an annual renewal process. The first two years are given in the form of an annual in-kind grant while year 3 can be provided as convertible loan note following successful incorporation.

As part of the funding, Bio Studio projects get access to BII's infrastructure, including offices, lab facility and an IT support package. For additional info on project funding, please refer to section 2.3 PROJECT BUDGET.

BEING PART OF THE BII COMMUNITY

BII believes our value lies in more than the money we provide, and we strive to foster a knowledge-sharing community that connects and supports innovators across the entire value chain. The BII building to serves as a networking hub to connect with like-minded innovators, and we encourage all users to embrace a culture of openness, collaboration, and knowledge exchange.



Being physically present at BII, the Bio Studio teams 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.

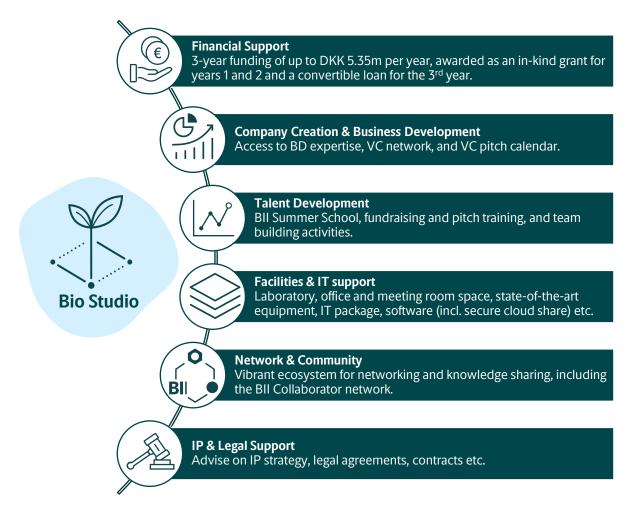


Figure 1: Bio Studio Content Overview

ACCESS TO BII'S ACCELERATION PROGRAM

As part of Bio Studio, project teams will gain access to BII's Acceleration Program, a platform designed to support projects and startups from early-stage research to market readiness. Throughout the project's lifetime, Bio Studio teams will work closely with other projects and start-ups in the BII Community, exchange knowledge and experiences and establish a supportive environment where innovation grows. Examples of the activities the project team will participate in during the program are:

Halos: A unique part of BII's offering, which are small-group coaching and peer-support sessions set up in a confidential frame, designed to support the psychological resilience of founders and EiRs and to help them navigate the emotional and interpersonal challenges of building a startup.

Bootcamp: This 3-day event serves as an introduction to BII's collaborative environment and is used to set the expectations for the journey ahead and establish a shared understanding of what it means to be part of the BII Community.

Vertical Summit: These sessions take place twice a year and bring together all projects and startups working within the same of Bll's Verticals, such as Therapeutics, Planetary Health, Health Tech, or Quantum Technologies. They provide a space for all teams to discuss relevant topics and exchange field-specific insights and are designed to enhance knowledge-sharing within the community.



Demo Day: Once a year, BII opens the doors to celebrate all the projects and startups in the BII community. At this event, Bio Studio projects will be able pitch their projects to investors, researchers, industry leaders, and entrepreneurs from across the ecosystem.

Orbit Learning Platform: All team members can access BII's learning platform Orbit, which provides a rich array of resources and modules tailored to support entrepreneurial and scientific advancement. These include courses and seminars on topics such as IPR, pitch training, fundraising, developing entrepreneurial competencies, and many more.

Investor Network: As part of BII's mission to bridge the gap between research and commercialization, BII has built a global investor network designed to connect early-stage startups with venture capital firms, corporate investors, and strategic advisors. Throughout the project, teams are invited to pitch to potential investors, who will provide crucial feedback on the development of the project.

1.4 PROJECT AND TEAM MANAGEMENT

Bio Studio allows the PI to establish a satellite group at BII in Copenhagen. Here, the team work towards formation of the new spin-out company within the 3-year project period. The project will be led by an EiR who will be the day-to-day manager of the team at BII, while the PI will drive the scientific direction of the project.

A typical Bio Studio team will consist of the PI, the EiR, and 3-5 team members. The team members and the EiR will be employed by BII and are expected to be primarily working at BII's premises. BII 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, a senior member of the PI's research group will transfer to BII and become part of the Bio Studio Team to ensure efficient technology transfer to the project.

At BII, the EiR takes the role of as the "CEO", is the driver of company creation by owning the milestone plan, engaging with investors, and overseeing fundraising and communication of the project. The EiR also serves as the primary contact for the PI on the activities at BII.

The project will be supported by a dedicated BII Anchor who work closely with the EiR and the Project Team to guide the project, product and business development throughout the 3-year period at BII.

PI Principal Investigator	EiR Entrepreneur in Residence	BII Anchor Bio Studio Anchor
The PI provides scientific leadership and strategic input without managing daily operations.	The EiR is the daily operational lead, responsible for team management, and drives company creation.	The BII Anchor connects projects to BII's network and supports strategic and operational tasks.
They coordinate between the home university and BII, sign grant agreements, and ensure early tech transfer by ensuring alignment with the TTO. The PI also supports communication, team alignment, and contributes to the milestone plan and reporting.	They lead the team, develop the business plan and strategy, pitch deck, and investment case, while leading fundraising efforts. The EiR also coordinates with the PI and Anchor, engages with external partners, owns the milestone plan, and runs the Project Board.	They manage due diligence, identify project gaps, oversee milestone and budget, and ensure timely submissions for board reviews. The Anchor also helps with hiring, onboarding, and portfolio acceleration while serving on the Project Board.

Figure 2: PI, EiR, and BII Anchor roles and responsibilities

1.5 MILESTONES, PROJECT PROGRESSION, AND OWNERSHIP

Prior to project start, the BII Anchor will work with the EiR and PI 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 - a key milestone or event that significantly increases the value of the project/company - in relation to key scientific, business development, and team milestones to be reached during the project.

Project progression will be closely monitored at regular progress review meetings between the EiR, the BII Anchor, and potentially the PI. Annual extension of the grant is approved by the BII Board of Directors (BoD) based on progression of the milestone plan. If the project is unable to meet critical milestones, it may change direction or be discontinued if it is determined that continuation is not feasible.

For any translational project, a broad range of interdisciplinary skills and expertise across various areas are required. 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. During the first year, the PI and team will also align on the cap table 1 for the prospective company.

1.6 BIO STUDIO SPECIFIC 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 home institution of the PI if the necessary infrastructure capabilities are not available at BII or via contract research organizations. The PI 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 meetings and events relevant to the project, such as the kick-off Bootcamp, the annual Demo Day, Project Board meetings, etc.

INTELLECTUAL PROPERTY RIGHTS (IPR)

As a commercial foundation with a non-profit objective, BII has no economic stake in any future spin-out company generated within Bio Studio and takes no royalties on project-generated IP. BII does not claim ownership of any IP generated prior to or during the Bio Studio project. 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) and all IP rights will be handled according to this agreement. 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 home 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. Applicants must be entrepreneurial academic group leaders with an innovative project idea solving a challenge with large potential impact and commercial potential; however, no company must be formed. The purpose of Bio Studio is to establish new spin-outs after the grant period and not to support existing companies.

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¹ A cap table, short for capitalization table, is a document that details a company's equity ownership structure.



2 APPLICATION PROCESS

2.1 ELIGIBILITY CRITERIA

Bio Studio is a strategic effort where BII continuously and actively sources projects that match the themes within BII's priority areas (see section 1.2). Every 6 months, BII launches a Bio Studio challenge within a strategic area of interest with high unmet needs and large innovation potential.

In addition to being in scope for the current challenge as per the challenge description (see our <u>website</u> for further details on upcoming and current challenge calls), the projects are expected to meet the criteria outlined in Table 1 to be considered for Bio Studio.

Principal Investigator (PI)

- Associated with a Danish or interantional university, hospital or other research institution.
- Strong academic track record considering the career stage of the Pl.
- Professor, Associate Professor 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).

Science and Technology

- · Scientifically founded technology with publication track record
- The translatability must be evident and documented through internal indicative data in a relevant model that is accepted in the field.
- The scientific outcome addresses the current BII Challenge and has potential for creating high impact.
- The science and technology must be transferable to BII.

Commercial Potential

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

Team

- Only one PI (the applicant) is accepted per Bio Studio project. A collaborating PI can be included as project adivsor however co-PIs are not accepted.
- Indication that at least one scientist (not a PhD student) key to the project can transfer from the Pl's group to BII.

ΙP

- 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 home 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 1.6.

Table 1: Eligibility Criteria for applying to Bio Studio

2.2 EVALUATION CRITERIA

Project proposals will be evaluated based on the overall criteria outlined in Table 2 below. These criteria are revisited at all stages throughout the extensive Bio Studio evaluation process described in section 2.3.



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 difficult 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 is differentiated 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 sufficient follow-up funding by the end of the 3-year program

Table 2: Evaluation criteria for Bio Studio

key equipment required for initiating the project.

2.3 APPLICATION & EVALUATION PROCESS

The project must be within the scope of the current BII challenge and/or focus area (see our <u>website</u> for further details) in addition to the criteria outlined in Table 1 to be considered. If interested in applying, you are welcome to reach out on <u>BioStudioProgram@bii.dk</u> to hear more about the running challenge and upcoming application deadlines, or enquire about Bio Studio and scope.

Applications must be submitted via BII's funding platform <u>ATLAS</u>. Throughout the application process, additional and application material must also be submitted through ATLAS upon request as outlined in the sections below.

Project proposals are evaluated in a process involving multiple internal and external stakeholders, who will decide whether a proposal will progress to the next assessment stage. Throughout all stages of the application process, the applicant will work closely with a primary BII contact person as well as additional BII staff to address any questions or supply additional information as requested.

The proposal evaluation process takes approximately 6-7 months from the submission of the initial Expression of Interest (EOI) to final approval. Throughout this process the PI and the BII contact person will work together to mature the project plan. If approved, the anticipated time from BII BoD approval to project start is approximately 4 months for Danish projects and 4-10 months for international projects². The overall assessment stages and expected timeframes are outlined in Figure 3 below.

² Danish projects are expected to begin faster where a collaboration agreement is already in place between BII and the PIs home 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



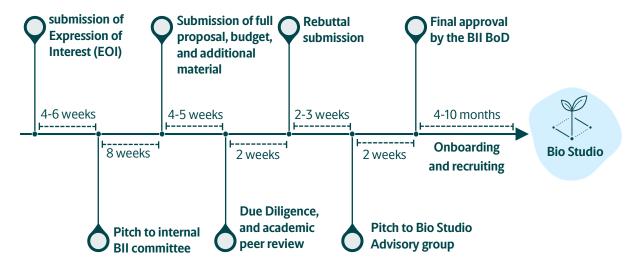


Figure 3: Assessment stages in the Bio Studio proposal evaluation process

EXPRESSION OF INTEREST

The initial step of the application process is the submission of an expression of interest (EOI) and a short PI CV. The EOI is a short application format covering:

Team

Describing the envisioned project team, including a description of profiles of the key project staff: PI, EiR, and Lead Scientist. Also include describe who from the PI's research group will be responsible for the tech transfer to the BII team and any personnel transfers from PI's group.

• Impact and value proposition

Detailing the unmet need and the specific problem the project aims to solve, including current gaps and how the solution aims to address these.

• 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 the project idea.

Business Model & Market

Explaining the intended business model and the potential market for the proposed solution.

• Project Plan & Milestones

Outlining the key development activities and milestones (within the areas of science, IP, and business development) for the proposed project.

References

PITCH TO INTERNAL BII COMMITTEE

Upon positive outcome of the evaluation of this EOI, the applicant will be invited to pitch their project to a committee consisting of BII evaluators and potential external advisors. This pitch is mainly focused on the scientific and technical aspects of the project and should be no longer than 20 minutes followed by 10 minutes Q&As. Following the pitch, the BII Team will assess whether the project will progress to the next assessment stage.

FULL PROPOSAL, BUDGET AND ADDITIONAL DOCUMENTS

If the internal BII committee decides to proceed with the project, the applicant will be invited to submit a full proposal. During the proposal phase the PI will be invited to an interview with People & Organization at BII. This is done to ensure that the PIs values are aligned with those of BII and that the purpose of Bio Studio is clear.

The applicant will have 4 weeks to submit their proposal using a template provided by BII, followed by a 2-week revision period in collaboration with the BII Team. The proposal will cover the sections below:



Team

Describing both the academic experience and any commercialization/entrepreneurial activities of the PI. Specifying the envisioned project team, including a description of profiles of the people that that will be hired for the team, including any transfers from the PI's research group. If a team member is not 100% based at BII or 100% allocated to the project, this must be specified. If relevant, also include collaborators, specifying their key competencies and contribution.

• The problem and impact

Detailing the unmet need and the specific problem the project aims to solve. Describing any areas of the problem, the solution does not cover and how this will be mitigated. Detailing the impact of the proposed solution for the benefit of human or planetary health.

• The solution and key data

Describing the scientific basis of the technology, adding key experiments that validate the proof of concept for the solution.

Commercial strategy

Detailing the commercial strategy and market opportunities, including the path to market, timing, competitor analysis, regulatory requirements and current IP status.

Project plan

Specifying the scientific development plan, business development plan, IP, and funding activities that must be executed during the project. a milestone plan and/or Gantt chart must be included, listing the key scientific and business deliverables and measurable milestones associated with these.

• Infrastructure and equipment

Outlining the equipment needed while incubated at BII, including any special permitting/MTAs required

Background IP

Specifying if any existing project-relevant IP will be used as part of the Bio Studio project.

Foreground IP

Describing any IP that is relevant to the project and not yet files and will be generated during the time in Bio Studio.

References

PROJECT BUDGET

When submitting the proposal, the applicant is also asked to prepare a Project Budget of up to DKK 5.35m (EUR ~0.72m) per year. The budget may include a cash out amount for activities that must operate from the home institution. In broad terms, the Project Budget must detail:

Salaries of staff

For team members who will be hired during the 3-year project timeline, including relocation and recruitment costs for the EiR and all other research staff.

Expenses

Covering business development, team and culture building, travel for PI and staff, and outsourced experiments or manufacturing costs. Furthermore, expenses for project-specific equipment (including large and equipment, and special IT) and consumables not currently available at BII. Please see list of equipment available at BII here: www.bii.dk/about/laboratories/.

IP expenses

An earmarked portion of the project budget will be allocated for IP-related expenses to ensure that this is budgeted, unless otherwise argued.

• Third party contribution

Required only if the project has received co-financing from the PI's home 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).



In addition to the Project Budget, BII covers the following expenses for the duration of the project:

- Rent at BII including access to BII infrastructure with laboratories and office space
- Standard BII IT package (laptop, monitor, mouse, keyboard, phone and Office 365) and IT support.
- Operational support by BII staff, such as legal, finance, and communication support.

For a detailed overview of what can and cannot be covered by the Project Budget, please refer to Appendix 3.2.

LETTERS OF SUPPORT

When submitting the proposal, the applicant must also provide the following letters of support acknowledging the support for the application:

- From the **PI's Department Head** acknowledging that the PI can engage in the project, and if relevant, can use home institution infrastructure as outlined in the proposal.
- From the PI's home institution Tech Transfer Office clarifying whether any Background IP is available
 for the project. If a collaborator is involved, this letter should also acknowledge the collaboration and
 suggest how to handle IP generated during the project.
- If the project involves a collaborator, such collaborator and their Tech Transfer Office must confirm their
 participation in the project and acceptance of IP terms described in Section 1.5. If the project depends
 on data/samples, access must be documented. For clinical samples, a support letter from the collaborator providing them is required.

DUE DILIGENCE AND ACADEMIC PEER REVIEW

After the full proposal and budget has been submitted, the proposal will go through commercial, scientific, and technological due diligence. BII uses an array of due diligence partners, to ensure that every aspect of the project is properly addressed. Additionally, the proposal will go through peer review for assessment by at least 3 academic experts identified by BII. All peer reviewers go through a conflict of interest check before receiving any material related to the assessment.

Based on the due diligence and peer reviewer feedback, the BII Team will decide whether to move forward with the proposal or not. Regardless of the project's progression, all due diligence and peer reviewer reports are shared with the applicant after the conclusion of this assessment stage.

REBUTTAL

Following peer review and due diligence, the applicant will receive feedback from the evaluation. Any questions or unaddressed points regarding the project that came up during the assessment will be compiled and the applicant will be asked to revise the proposal to address these questions. In this rebuttal, the applicant should respond to each point raised by the reviewers and due diligence partners, providing detailed explanations, additional data, or revised approaches as necessary.

PROGRAM ADVISORY GROUP PITCH AND FINAL APPROVAL

Upon completion of the rebuttal, the applicant will be invited to pitch for Bll's Bio Studio Advisory Group (BStAG), which consists of a panel of experts and investors in the field as well as Bll's executive leadership team. The pitch should be no longer than 15 minutes followed by 15 min Q&As. During this pitch, the focus should be on the project team and scientific excellence and should highlight the clear business potential of the project. Based on the recommendations from the BStAG, the BII BoD makes the final decision to authorize the BII CEO to approve the project.

COLLABORATION AGREEMENT

Once a project has been approved by the BII BoD, a collaboration agreement between BII and the PI's home institution must be signed. This agreement sets up the contractual framework for the parties' collaboration over the 3-year period of the Bio Studio program, and addresses key topics such as 1) BII funding, 2) project



management, 3) ownership and management of intellectual property and 4) spin out conditions (including licensing terms ensuring the spin out company access to foreground and background IP owned by the home institution).

The collaboration agreement is usually negotiated between the BII team and representatives from the Technology Transfer Office (TTO) of the PI's home institution. Once the agreement is signed, a grant letter is issued, marking the start of the project.

2.4 CONFIDENTIALITY AND DATA PRIVACY

We are committed to treating all applicant information confidentially. Our commercial due diligence partners, academic peer reviewers and BStAG have all signed confidentiality agreements, protecting your information and are instructed to destroy or return all documentation after the review period is completed. BStAG members and peer reviewers will declare a conflict of interest if they work on/with a similar project as proposed by the Applicant or have any conflicting relations with 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. We will process your information based on our legitimate interest³ in being able to enter discussions with eligible PIs for 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 legal@bii.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 privacy notice (<u>bii-privacy-notice-27012025.pdf</u>).

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 legal@bii.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.

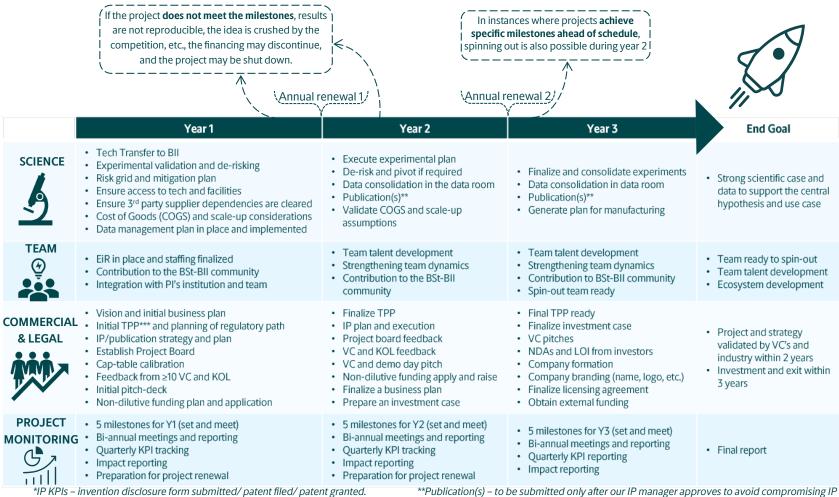
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³ General Data Protection Regulation (GDPR) Article 6 (1) (f).



3 APPENDICES

3.1 EXAMPLE OF A PROJECT MILESTONE PLAN



***TPP – Target product profile is a document that covers the IP, regulatory, market, target end user, details of product and manufacturing, intended attributes of product, etc.

Figure 4: Example of a Bio Studio Project Milestone Plan. Milestone Plan for each individual project is co-created by the Pl, the EiR and the BII Anchor.



3.2 BIO STUDIO PROJECT BUDGET SPECIFICATIONS

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).
- Project specific equipment currently not available at BII (refer to the BII www.bii.dk/about/laboratories/ for available equipment).
- Staff competencies development activities (e.g. BII-CBS Summer School, workshops, VC bootcamp, attendance at conferences or relevant scientific events).
- Travel costs 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.
- 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 covered. Costs relating to maintaining Background IP may be covered depending on the collaboration agreement between BII and home institution.
- Administrative/Overhead fee to a maximum 5% (only for a cash out part of the grant, if any).
- PI consultancy fee up to DKK 100,000 per project year.

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 Pl.
- Salary for PhD students.

Figure 5: Project Budget Specifications and Limitations



3.3 ABBREVIATIONS

ΑI	Artificial Intelligence	EOI	Expression of Interest
BD	Business Development	HR	Human Resources
BII	BioInnovation Institute Foundation	IP(R)	Intellectual Property (Rights)
BoD	Board of Directors	KOL	Key Opinion Leader
BSt	Bio Studio	KPI	Key Performance Indicator
BStAG	Bio Studio Advisory Group	LOI	Letter of Intent
CAP	Capitalization	LOS	Letter of Support
CBS	Copenhagen Business School	MTA	Material Transfer Authority
CDA	Confidential Disclosure Agreement	MVP	Minimum Viable Product
CEO	Chief Executive Officer	NDA	Non-Disclosure Agreement
COGS	Cost of Goods	PI	Principal Investigator
CRO	Contract Research Organization	Q&A	Questions & Answers
СТО	Chief Technology Officer	R&D	Research & Development
GDPR	General Data Protection Regulation	TPP	Target Product Profile
EEA	European Economic Area	TTO	Technology Transfer Office
EiR	Entrepreneur in Residence	VC	Venture Capital



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 EUR 2.2m per project and EUR 1.8m 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.

