APPLY BEFORE JANUARY 10

CALL FOR PROPOSALS

Need funding and support to further accelerate your life science commercialization journey? Apply to BIO-X Accelerate!

BIO-X ACCELERATE

New opportunity for Life Science projects. Faster development by financing, support and access to network of experts.

Global challenges, such as an aging population and the increase in lifestyle-related diseases put new demands on our capacity to translate discoveries into commercially viable health solutions for improved public and veterinary health.

Uppsala BIO invites Small and Medium-sized Enterprises (SME) from East Middle Sweden (Östra Mellansverige including Uppsala,Västmanlands, Sörmlands, Östergötlands och Örebro counties) to apply for BIO-X Accelerate. Funding will be in the range 3 MSEK up to 7 MSEK, with co-funding of approximately 50%. The funding comes from the Swedish Agency for Economic and Regional Growth (Tillväxtverket) and the general terms and conditions for the Swedish Agency for Economic and Regional Growth apply.

For companies who have completed their first in vitro / in vivo verification or technical validation and now need to take the next step in increasing value in their project, this is an opportunity to seek support for clinical evaluations, end-user validations or other key development activities (for more details, see below). After project completion, the goal is that your company will have significantly reduced any technical, business or market risks, enabling other investments and/or market introduction. The risk-reduction can be based on for example Safety-Tox activities, effectiveness, analytical and clinical diagnostic performance characteristics, biocompatibility, or scale-up of processes (for more examples see below). The goal is that the activities financed through the BIO-X Accelerate program shall make a significant difference to the value of the company.

Who can apply?

We invite SMEs developing innovative products, processes and services for improved public and veterinary health to submit project proposals. This includes areas such as pharma, medtech, diagnostic, eHealth, etc. The end solution can be a solution for any stage in the healthcare and/or veterinary care process, including prevention, diagnosis, treatment or a care regime. Companies encompassing other enabling biotech technologies, intended for research purposes, are also welcome to apply.

A BIO-X project should offer a new solution to a well-defined need and be based on evidence-based data.

After BIO-X the project should be ready for investment by for example industry or venture capital companies, for a future new product, method or therapy with a significantly new value for the patients, healthcare or society.

What activities can be supported?

Focus for the program will be on pre-clinical and clinical evaluations, end-user and other key development activities. Other supporting activities such as development of prototypes, testing efficiency and safety for new products, preparation of documentation for CE marking, development of quality systems, as well as documentation and permits in connection with clinical evaluations will also be supported.

We expect applications requesting support in the range 3-7 MSEK, corresponding to a total project budget of 6-14 MSEK co-funding included.

Accepted Technical readiness levels will be TRL 3-7, with some exceptions for “newly formed companies” which can include TRL 8 and 9 as well. For more details, please refer to “Frequently asked questions”.

Example project scopes:

- Testing of a medtech device in patients where the purpose of the project is to confirm that the device is both effective and safe (i.e. a limited but still statistically relevant clinical study)
- Testing of software, IT systems etc. in primary care, i.e. in 'real life' with both treating physicians and patients
- Testing AI technologies (e.g. computerized pathology) in a normal clinical flow to show that the product is at least as good as existing technologies and can save time and / or resources compared to current practice
- First-in-man (FIM) studies
- Exploratory clinical evaluations
- Testing the efficacy, safety and / or biocompatibility of a drug candidate, diagnostic or medical device, or other reagent
- Validation of formulation aspects, scalability and manu facturing / methods

Example project activities:

- Preparation of documentation needed in connection with clinical evaluations, e.g. ethical permit, permit from the Swedish Medical Products Agency etc. (salaries, submission fees etc.)
- Activities related to contracting of CROs and others
- Development of materials to be able to perform clinical validation
- Activities at the healthcare partner as part of the project
- Development of quality systems
- Activities before and in connection with the CE marking. Note! Only applicable for new products. Upgrading of existing quality systems as a response to new legislation is not in scope for this call.
- Safety / toxicological profiling of the intended product (consultants, CRO, etc)
- Technical verification and validation required to, for example, be able to conduct clinical validation (not basic verification / validation, but instead after any adjustments / changes made as a result of basic verification / validation)
- Manufacture of batch of drug candidate, diagnostic product or other reagent to determine its effectiveness and safety
- Manufacturing process scale-up and process validation

The latest phases of development accepted in this call:

- Pharmaceuticals: Up to Phase II and planning for phase III
- MedTech: Clinical safety and effectiveness trials using a fully integrated prototype version of the medical device in an operational environment. Validation of final product design and final prototype and/or device intended for commercial use produced and tested.

Not included – to late development phase for this call:

- Pharmaceutical Phase III studies,
- Preparation for product launch,
- New drug application or Biological License Application prepared and submitted,
- Premarket application or premarket notification submitted,
- Activities after product launch

In general, routine or recurring changes or updates of existing products, methods, services, or processes are not included in this call, although such changes may represent improvements.

Who can apply?

The call is open for SME* based in Östra Mellansverige, including Uppsala, Västmanlands, Sörmlands, Östergötlands and Örebro counties.

Are you unsure whether your SME, and your outlined activities, are in scope of this call? Please do not hesitate to contact us to discuss more!

**As defined in EUR-Lex - 32003H0361 – EN. In brief, an SME has up to 250 employees and a turnover of less than EUR 50 million or a balance sheet total of less than EUR 43 million.*

Level of funding and Co-funding

The level of funding will be defined by the state aid regulations, and depends on the applicants legal constitution (start-up company, small business, medium-sized enterprise and the scope of the proposed project (i.e. which paragraph the proposed activities fall under in the regulations). Typically, it is 50% for Industrial research, and 35-45% for Experimental research. Highest level of funding is 50% for all organisations.

The following types of co-funding will be accepted:

- Cash
- Own time or costs
- Consultant time and costs
- Loans

Other EU-funding or other national public funding cannot be used as co-funding.

BIO-X accelerate offers you

Funding

BIO-X Accelerate grants selected projects funding in the range 3 - 7 million SEK for a period of 24 – 36 months. The BIO-X funding covers about 50% of the project budget. The applicant cover the remaining costs, either in cash or in-kind.

Process support and access to expertise

Projects receive funding, continued support and project status review, and access to expertise within the BIO-X network. For more details, please refer to "Frequently asked questions".

Keep ownership longer

The SME retains full ownership of data and full confidentiality.

Increase your chances for success – support from advisors and access to networks

After project completion, the goal is that your company will have significantly reduced any technical, business or market risks, enabling other investments and/or market introduction. Supported by the Advisory Board experts, as well as getting access to a large network, your chances for successful project execution increases.

How are projects selected?

Representatives from industry and healthcare, together with investors, constitute the BIO-X Accelerate Advisory Board that selects the most promising proposals. The projects are selected based on the following criteria:

- Feasibility and Potential
- Implementation Strategy / Market Strategy
- Impact for society/citizens/healthcare systems
- Innovative height and IP strategy

About the BIO-X® accelerator program

BIO-X Accelerate is a further development of BIO-X in close collaboration with Tillväxtverket and Region Uppsala, with Uppsala Innovation Centre as partner, with the goal to accelerate the development of innovative life-science companies in the region. The program utilises an industrial approach to support early-stage, life-science related projects that could fulfil well-defined needs in healthcare and society. Projects receive funding, continued support and access to experts within the BIO-X network. The first critical step towards potential commercialization - 'proof of concept' - studies should already be performed when entering the program. After BIO-X the project should be ready for investment by for example industry or venture capital companies, for a future new product, method or therapy with a significantly new value for the patients, healthcare or society. BIO-X is a trademark of Uppsala BIO.

Let's talk

It's straight forward to apply for BIO-X Accelerate. Please download the BIO-X Accelerate Project Proposal Form from

https://www.uppsalabio.com/develop-your-idea/current-call/

We're here to help you with your application. Please do contact Uppsala BIO before sending your proposal. We are happy to give you feedback on your proposal, however, in order to achieve feedback your suggested application should be submitted January 03.

The deadline for project proposals is January 10th, 2020 at 22.00 CET. Application should be submitted to bio-x@uppsalabio.com.

Questions? Do not hesitate to contact us!

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