

Development and production of biologics

A call for proposals under the programme Next-generation Biologics

1 Executive summary

The Swedish government has given Vinnova and the Swedish Research Council (Vetenskapsrådet, VR) the joint responsibility to establish a national programme for protein research, method development and production of biologics.

Development and production of biologics is the second call for projects within the programme which has the purpose to develop Sweden into a leading country in the field. The budget for this call is SEK 40 million. Project grant period is 1-3 years and maximum funding per project is SEK 5 million.

Vinnova and the Swedish Research Council invite consortia consisting of at least two partners that should come from different sectors – academia (including research institutes), industry or healthcare – to send in applications for funding for collaborative projects.

Proposals should concern important aspects of the development and production of biologics. Research could cover both research on future biologics and the development of efficient methods for production of next generation biologics. All proposals should aim at solutions with positive economic, societal and environmental impact.

Last application date is 8th of June 2017, 14:00 CET

Current information on the call, the invitation, templates and link to the proposal service are found at www.vinnova.se under "Utlysningar".

2 Background

Vinnova is Sweden's innovation agency within the Ministry of Enterprise and Innovation. Vinnova develops Sweden's innovation capacity for sustainable growth. The Swedish Research Council is an authority within the Ministry of Education and Research. The Swedish Research Council has a leading role in developing research of the highest scientific quality and thus contributing to the development of society.

The Swedish government has given Vinnova and the Swedish Research Council the joint responsibility to establish a national programme for protein research, method development and production of biologics.

2.1 The programme Next-generation Biologics

This research programme is part of the Government's strategic investment in life science that as a whole shall contribute to improved health, to meet societal challenges, strengthen Sweden's position as a leading country in research and development and to improve Sweden's competitiveness in an international context.

Biologics (biological medicinal products) are drugs where the active substances have a biological origin. In this programme, a broad definition of biologics has been adopted, which includes recombinant proteins and other macro-molecules, antibodies, vaccines, blood/plasma-derived products, non-recombinant culture-derived proteins, and cultured cells and tissues.

2.2 Goals of the programme

The purpose of the programme is to develop Sweden into a leading country in development and production of biologics.

The goals of the programme are:

- To create new knowledge on next-generation biologics
- To prepare the healthcare system for taking on new biologics
- To make Sweden attractive for cooperation and investments in research and development
- To increase competitiveness of companies in Sweden in an international perspective
- To promote and develop cooperation between academia, industry and healthcare
- To develop more efficient methods for the production of next-generation biologics

An overall goal of the programme is to contribute to a sustainable development in all three perspectives: economic, societal and ecological.

Economic sustainability implies an economic development not resulting in negative consequences for societal and environmental sustainability.

Societal sustainability implies a society where the rights of all individuals are respected. All individuals shall on equal terms be offered living conditions where they feel involvement and can absorb knowledge, growth and have good health.

Environmental sustainability implies that the production of goods and services matches the regenerative capacity and regulating functions of ecosystems. Development should be characterized by the use of renewable resources and economizing with available resources.

3 Call for proposals: Development and production of biologics

The purpose of the call is to develop Sweden into a leading country in development and production of biologics.

3.1 Who can apply

The call for proposals is intended for consortia, consisting of **at least two partners** that should come **from different sectors**: academia (including research institutes), business or healthcare. One partner needs to be designated principal applicant (coordinator). See Formal application requirements in section 5.

A project partner must be actively involved in the design and implementation of the project, and share the associated risks and outcomes. (For more information on the role of the project partners, see Vinnova's general terms and conditions.)

A participating company receiving funding should be registered as a joint-stock company (Swedish term: aktiebolag), with a recognizable record of research and development and industrial or commercial activities.

International partners are welcome to participate in the proposed project, but not as the coordinator. An organization registered abroad must have a branch/establishment in Sweden to be able to receive funding.

3.2 Scope of the call

Proposals should concern important aspects of the development and production of biologics. Research could cover both research on future biologics and the development of efficient methods for production of next generation biologics. All proposals should aim at solutions with positive economic, societal and environmental impact and thus be able to contribute to a sustainable development.

Proposals should be for research and development projects where the partners (see section 3.1 above) collaborate to find new solutions for efficient development and production of biologics. Proposals aiming at generic solutions for increased knowledge are expected, rather than applications that concern single drugs or treatment.

Research and innovation infrastructures that are proven suitable can be used to add competence and networks, but cannot be coordinators or project partners. Examples of infrastructures are quality registers, biobanks, testbeds/innovation support centre, research platforms, innovation offices and incubators.

Gender equality is an important aspect to consider when proposing a project. Women and men should have the same opportunities to gain from the grant. Both men and women should take part in the project activities, as well as in the decision-making in the project team. Gender balance in the project team is expected to be at least 40/60 percent. Projects that may result in increased gender equality are encouraged.

3.3 Expected results and impact goals

Expected results of this call:

- Scientific breakthroughs published in high-impact journals
- Established collaboration between academia, industry and healthcare
- New disruptive technologies for development and production of biologics

Contribution to the goals of the programme (cf. section 2.2 above):

- Sweden attracts new investments and collaborations in the area of biologics
- The healthcare system is better prepared for taking on new biologics
- More efficient methods are used for development and production of next-generation biologics
- Increased competitiveness for companies in Sweden in an international perspective

4 Application

4.1 How to apply

Applications are to be submitted electronically via the application service contained within Vinnova's eService's Portal. The application consists of a form and a number of annexes and can be accessed at www.vinnova.se.

In order to submit an application, you must first create a user account with Vinnova. This account can then be used to log in to the application service. If you already have a user account with Vinnova, you do not need to create a new one.

Those who submit applications must be authorized to do so on behalf of the applying organization.

Please note that all applications must have been received by 14:00 on the day of the application deadline. After this time, the system will close and it will no longer be possible to submit an application to Vinnova. No additions or changes can be made to the application after the deadline, unless requested by Vinnova.

Remember that filling in, uploading and submitting your application may take some time, especially if there are a large number of applicants. For this reason, make sure to begin filling in your application well ahead of the deadline. Please note that it is possible to save changes and additions up to the point when you submit the application.

4.2 Content of the application

The application consists of an electronic form to be completed by the applicant on the Vinnova eService's Portal.

In addition, a project description, a CV appendix and a budget should be attached to the application. The attachments shall be in PDF format.

We encourage all applicants to submit their application in English, as the assessment will be performed by an international panel.

Mandatory information in the Vinnova portal

- Project title in Swedish and English
- Summary in Swedish and English
- Partners and eligible costs for each partner
- Goal
- Need, potential and benefits
- Ethics

The project description must be written in the **specific template** for the application, which can **be retrieved from the website of the call**. The description may be a maximum of 10 portrait A4 pages, single column, 12 pt, black font. References to information on websites etc. will not be considered.

Information to be provided in the project description, in the given order

- Specific aims of the project

- Project idea and potential
- Background
- Impact for health sector, industry and/or society
- Project advantages in an international comparative perspective
- Assessing the cost-benefits balance
- Implementation plan
- Preliminary results/ pilot studies
- Work packages and timeline
- Communication of results
- Project participants, roles, and management

The CV appendix must be written in the **specific template** for the application and include CVs of the project manager, at least one representative for each of the project partners, and other key members of the project team. Each CV should be no longer than 1 A4 page, written in 12 pt, black font.

All project partners must be included in the CV appendix, as well as in the budget on the portal, regardless of whether the project partner is applying for funding or not.

The budget must be written in the **specific template** for the application.

5 Formal application requirements

To qualify for an assessment by Vinnova and the Swedish Research Council, in accordance with the criteria stated in section 8.2 below, the following requirements must be satisfied:

- The consortium should consist of at least two partners that should come from different sectors: academia (including research institutes), industry or healthcare of which one is to be the coordinator
- The consortium must consist of both men and women
- The project partners must be legal entities
- An organization registered abroad must have a branch/establishment in Sweden to be able to receive funding
- The application must include all mandatory attachments, written in English or Swedish
- The attachments should be correctly completed in the mandatory templates for this call
- A project may not apply for project time more than 3 years or a budget over SEK 5 million

Please note that any additional attachments that result in an application exceeding the maximum 10 pages allowed for the project description automatically means that the application is disqualified.

6 Budget and conditions for funding

6.1 Budget

The budget for this call is SEK 40 million. Project grant period is 1-3 years and maximum funding per project is SEK 5 million.

6.2 Conditions for funding and state aid rules

The eligible costs of individual project partners (the costs incurred by each project partner to implement the project) can entirely or partly be covered by grants from Vinnova. The part covered by Vinnova constitutes the so-called aid intensity and is stated as a percentage. The maximum aid intensity is determined per grant beneficiary, with different rules for different types of organizations and projects.

Eligible costs are determined based on the nature and content of the project and is set out in Vinnova's terms and conditions. The document "**Guide till Vinnovas villkor om stödberättigande kostnader**" (Guide to Vinnova's rules on eligible costs) clarifies which costs are considered eligible.

Small and medium-sized enterprises may receive up to 70% of their total budget for the project. Large companies are encouraged to participate but will receive no funding. Participants from academia, research institutes and healthcare may receive up to 100% of their total budget for the project, provided that the project is part of their non-economic activities.¹

Funding will not be given for any activities done before project start.

Grants from Vinnova and other governmental organizations awarded to businesses and other organizations conducting economic activities are limited by the rules on state aid. The rules entail that, in most cases, the company or organization will only get a grant for a certain proportion of its eligible costs or up to a limited amount.

Grants to companies and other organizations conducting economic activities are awarded on the basis of Vinnova's regulation (SFS 2015:208) on government funding for research, development and innovation. Each project partner is

¹ Economic activities means activities performed in competition with others. If the participant from academia, research institutes or healthcare conducts both economic and non-economic activities it is required that costs and funding for the two types of activities are separated. If the accounting is not separated, the organization will be considered as a company. This applies also to non-profit organizations, when activities are performed in competition with others.

independently responsible for ensuring that the grant received does not exceed the support level permitted in accordance with the rules on state aid.

7 Schedule

The following dates apply to the call:

Call opens: 7th of February 2017

Last application date: 8th of June 2017, 14:00 CET.

Interviews: End of September 2017 (only selected proposals; see section 8.1)

Final decision date: October 2017

Last date for project start: 1 November 2017

8 Assessment

8.1 Assessment process

Applications meeting the formal requirements will be assessed in competition with all other applications, on the basis of the electronic application submitted to Vinnova.

They will be assessed according to the assessment criteria, stated in section 8.2 below, by an international panel, including persons from both academia and industry. Interviews will be performed with the collaborating partners of the proposals receiving the highest ranking from the international panel. Vinnova and the Swedish Research Council will make a common, final decision regarding funding of selected proposals, based on the ranking made by the international panel, information collected during the interviews and the contribution of the proposals to the programme portfolio.

The formal decision will be communicated from Vinnova to the coordinator of each application.

8.2 Assessment criteria

The project should be consistent with the goals and purpose of the call. This will be assessed with the help of the following criteria:

Potential and scientific quality

- Relevance of the project in relation to the objectives of the call
- Innovativeness and novelty of the project idea
- Scientific quality of the research hypotheses and methodology
- Potential of the project to contribute to increased competitiveness of Swedish life science industry

- Potential of the project to contribute to improved health care
- Potential of the project to affect industrial processes, profitability and business models positively
- Economic, environmental and societal, including the equal opportunities perspective, impacts of the project

Feasibility

- Approaches chosen to reach the project goals
- Credibility of the budget and project plan, including timeline, milestones and activities
- Collaboration between project partners and other stakeholders of significance to the project
- Ethical considerations
- Risk assessment of the project
- Measures taken to achieve a positive economic, environmental and societal impact of the project
- Plan for implementation and utilization of the results, including IPR-strategy

Participants

- Overall skills and experiences of the members of the project group; mainly of the project manager and other leading project participants
- Relevant competence in the team i.e. engineering skills, competence on business models, scientific expertise etc. Involvement of the project partners (actors) in the project, with working hours and other resources
- Gender balance of the project group
- Involvement of end users and recipients (e.g. patients, clients, customers) in the project.
- Knowledge of competitive projects and environments worldwide and ability to position oneself accordingly

9 Terms and conditions

Vinnova's general conditions for grants, valid at the time of the decision, apply to the call for applications. The conditions contain rules on reporting, project contracts, follow-up, accounting and Vinnova's conditions for payment. Vinnova's general conditions are available under "Conditions and rules" on the website of the call for applications.

10 Confidentiality issues

Applications in response to the present call are public documents. As a general rule, the public has the right to view these documents in accordance with the

principle of public access to official records. This also applies to applications which are rejected or withdrawn. Vinnova's decisions and justifications for decisions are also considered public documents.

However, Vinnova has an obligation to maintain the confidentiality of all information concerning an individual's business or operational circumstances, discoveries and research findings, if their disclosure could be considered financially damaging. More detailed information on confidentiality rules for applications are available on the web page on "Sekretess vid ansökningar" (Confidentiality in applications) which can be accessed from the website of the call for applications.

For more information, see "Juridisk information" (legal information) on www.vinnova.se under "Om Vinnova".

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