

Protein Research and Process Development for Biologics

A call within the Next-generation Biologics programme

The call is issued in collaboration with the Swedish Research Council





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1 Call in brief

By means of this call, we wish to reinforce Sweden's position within biologics.

The call has two focuses:

- **Protein Research**, aimed at developing protein-based pharmaceuticals that enable improved treatment
- **Process Development**, to improve the manufacture of biologics through new or improved existing technology

The applicant shall state the focus of the application in the application form. Applications will be assessed in competition with the other applications received within each focus.

The project shall consist of at least one company with research, development or production in Sweden and at least one academic participant, from a higher education institution or a research institute. One of these participants shall be the main applicant (coordinator). The participants shall have developed the project proposal jointly.

The call covers two separate project sizes, with partially differing terms and conditions:

- **Projects with grants of up to 5 million SEK**
These are awarded with a requirement for co-funding according to the regulations for government support to companies and other organisations carrying out economic activities
- **Projects with grants of up to 10 million SEK**
For these projects, in addition to the requirement above, at least 50 per cent of the overall project cost shall be co-funded by the project participants using non-public funds

The project period may vary between 1 and 3 years, for projects of both sizes.

The overall budget for the call – covering both focuses and both project sizes – is 60 million SEK.

The following dates apply for the call:

Please note that the dates are preliminary. For up-to-date information, please see www.vinnova.se.

Opening date	4 September 2018
Closing date	15 January 2019, 14.00 CET
Interviews, selected applications	5–8 March 2019



Last decision date	1 April 2019
Earliest project start date	1 April 2019
Latest project start date	1 July 2019

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Up-to-date information about the call and a link to our application service is available on www.vinnova.se.

2 What do we want to achieve with the funding?

The purpose of the call is to give Sweden a leading role within the area of biologics, through developing process technology and using prominent protein research. The proposals should aim at generic solutions and broadly applicable knowledge, rather than developing individual pharmaceuticals and therapies.

The projects shall have one of the following two focuses:

- **Protein research for biologics**

The focus relates to projects that use results from the research frontier within protein research to create new and ground-breaking methods and technologies for development of improved protein-based pharmaceuticals. Applications shall describe an innovative idea with a clear goal for development of protein-based pharmaceuticals.

The research may, for example, include improved antibodies or recombinant proteins, glycoengineering, targeted delivery or new formulations that considerably improve the opportunities for development of protein pharmaceuticals and in the end, enables improved treatment.

- **Process development for biologics**

The focus relates to projects that aim to develop the process technology for production of biologics. The development may entail either developing new technology or improving existing technology, so that the manufacture of biologics becomes easier, cheaper, more robust and/or more efficient, and also to a greater extent scalable.

In this context, a biologic is a preparation whose active substance has been produced in or refined from material of biological origin. For projects focusing on process development, a broad definition is used which includes recombinant proteins, antibodies, vaccines, blood and plasma products, macro-molecules, non-recombinant proteins from cell cultures and also cultured cells and tissues.

We encourage multi-disciplinary projects in particular. In these, competences from various subject areas or disciplines that complement each other collaborate.

We also wish to stimulate new collaboration, between participants that have not worked together previously.

The call will contribute to increased capacity to reach the global goals for sustainable development in Agenda 2030, by supporting research and innovation linked to improved health and medical care and/or production of pharmaceuticals.

Another starting point is that gender equality is one of our strongest tools for achieving the goals of Agenda 2030. The call shall therefore contribute to gender-equal social development, where women and men on equal terms partake of the grant, have influence over the project and contribute actively to its

implementation, and where the project results contribute to increased gender equality.¹

3 Who is the call aimed at?

The project shall consist of at least one company with research, development or production in Sweden and at least one academic participant, from a higher education institution or a research institute. One of these participants shall be the main applicant (coordinator). The participants shall have developed the project proposal jointly.

A company receiving a grant shall be registered as a limited company working actively within research and development and business.

Participants from health and medical care, for example, may add value to the project, as a project participant or stakeholder, but can neither replace the business participant nor the academic participant.

International participants are welcome to take part in the proposed project, but cannot be the project coordinator. Organisations registered outside Sweden must have a branch office or operating site in Sweden in order to receive a grant.

If there is a need, suitable research and innovation infrastructures may be used to add competence and networks, but these cannot be the coordinator or project participants.

4 What do we fund?

4.1 Activities you can apply for funding for

Activities within collaboration projects of the type “Industrial Research” or “Experimental Development” according to the definition in Vinnova’s funding regulations are funded in this call.²

¹Read more about what our work towards gender-equal innovation means for you as applicant for a grant from us: <https://www.vinnova.se/m/jamstallid-innovation/>

² See the description in the document Stödnivåer, definitioner m.m. för bidrag enligt Vinnovas stödordning (Support levels, definitions, etc. for grants according to Vinnova’s funding regulations) <https://www.vinnova.se/globalassets/huvudsajt/sok-finansiering/dokument/stodnivaer-statligt-stod.pdf>

4.2 Costs eligible for funding

Our funding is paid out as grants. Grants to organisations carrying on business activities are covered by regulations for government funding.³ The regulations govern matters such as the type of costs and the percentage of them that can be covered by a grant.

The costs stated in Vinnova's general terms and conditions for grants – 2018, Section 6.1 are eligible for funding on condition that they are calculated and reported according to the Guide to Vinnova's conditions on eligible costs.⁴

Research organisations and health and medical care organisations can receive grants of up to 100 per cent of their costs eligible for funding in their non-economic activities.⁵

5 What is our grant amount?

The call covers two separate project sizes, with partially differing terms and conditions:

- **Projects with grants of up to 5 million SEK**
These are awarded with a requirement for co-funding according to the regulations for government support to companies and other organisations carrying out economic activities
- **Projects with grants of up to 10 million SEK**
In addition to the requirement above, at least 50 per cent of the overall project cost shall be co-funded by the project participants using non-public funds

The project period may vary between 1 and 3 years, for projects of both sizes.

The overall budget for the call – covering both focuses and both project sizes – is 60 million SEK.

³Read more about government funding on our website: <https://www.vinnova.se/en/apply-for-funding/rules-for-our-funding/state-aid-to-companies/>

⁴Our General terms and conditions for grants and the Guide to Vinnova's conditions on eligible costs can be found on our website: <https://www.vinnova.se/en/apply-for-funding/rules-for-our-funding/terms-and-conditions-for-our-funding/>

⁵Economic activities refer to activities carried out in competition with others. If the research organisation or care provider carry out both economic and non-economic activities, it must be possible to differentiate the costs and funding for each type of activities clearly. If there is no separate financial reporting, the organisation is regarded as a company. Whether an organisation is for-profit or not-for-profit is of no importance for the issue of whether its activities are economic or non-economic. Of importance is if the activities are carried out in competition with others.

6 Prerequisites for assessing applications

We will only assess applications that fulfil the following formal requirements:

- The project shall consist of at least one company with research, development or production in Sweden and at least one academic participant, from a higher education institution or a research institute
- The coordinator shall be a Swedish organisation and consist of a company or an academic participant
- The project participants are legal entities
- Companies applying for grants shall be registered as limited companies
- The application shall be written in Swedish⁶ or English
- The application shall include all mandatory appendices according to Section 9, written using the mandatory templates within the framework for the stated maximum number of pages
- The application shall contain no appendices over and above the mandatory appendices
- For projects with a grant amount applied for in excess of 5 million SEK, the participants' co-funding with their own input shall amount to at least 50 per cent of the project's overall costs eligible for funding

7 Assessment of applications received

7.1 What do we assess?

Applications that fulfil the formal requirements will be assessed on the following three criteria, each consisting of a number of subsidiary criteria:

Potential and scientific quality

- The relevance of the project in relation to the purpose and aims of the call
- The novelty and the degree of innovation of the project idea
- The extent to which the project idea is focused on generic solutions and broadly applicable knowledge
- The extent to which the project is multi-disciplinary
- Scientific quality of the question and method, and the potential to contribute to new advances
- The project's potential to have a positive impact on industrial processes, profitability and business models

⁶Applications written in Swedish will be translated by a procured translation agency; this will be done by Vinnova and cannot be appealed.

- The project's potential to contribute to increased competitiveness of Swedish industry in an international perspective
- The project's potential to contribute to improved health and medical care
- The project results' potential to contribute to increased gender equality

Actors

- Knowledge, competence and experience of the project group members; in particular of the project manager and other key persons
- Access to relevant competence in the project group, such as technology, business models and science
- The actors' ability to describe and position themselves in relation to competitors and collaboration opportunities, both nationally and internationally
- The project participants' engagement in the project, with working hours and other resources
- Existence of any new collaboration between project participants who have not previously collaborated
- Engagement of end users and others who may benefit from the project results
- How well the team (and key persons) is composed in terms of gender division, and the division of power and influence between women and men

Feasibility

- A project plan that clearly describes how the activities listed will be implemented
- Plans and activities showing the engagement, participation and internal communication of all participants
- The project's activities, time plan and milestones are realistic and relevant in relation to what is required to reach the expected results
- A reasonable budget and credibility of funding and access to other resources for realisation of the project
- Relevance and credibility in the risk analysis presented by the applicant for the project
- A credible plan for implementing and using the project results and for using the data produced, as well as an IPR strategy⁷
- Ethical considerations, where relevant
- How well gender equality aspects have been integrated in the project plan

⁷Strategy for Intellectual Property Rights

7.2 How do we assess applications?

The assessment is made in competition between applications received.

The applications that fulfil the formal requirements will be assessed by international experts. They will be assessed and ranked in two groups: protein research and process development respectively.

The highest ranked project proposals in each group will be called for an interview, where at least one representative from each project participant and other key actors are expected to take part. The interviews aim to clarify any uncertainties in the applications, and to make clear the collaboration between the participants in the project.

Following the interviews, Vinnova and the Swedish Research Council will jointly decide on which projects that can be considered for funding.

The formal decisions are taken and communicated to the applicants by Vinnova.

8 Decisions and terms and conditions

8.1 About our decisions

The amount awarded to each participant in a project is stated in the decision. Grants will be awarded based on Vinnova's Regulation SFS 2015:208. The legal basis for the aid is shown in the decision, and also directs which costs are eligible for support.

Our decision to award or reject an application cannot be appealed.

8.2 Terms and conditions for grants awarded

Our general terms and conditions for grants apply to grants awarded.⁸ The terms and conditions include rules governing project agreements, prerequisites for payment, follow-up, reporting and utilisation of results.

In addition to the general terms and conditions, the following specific terms and conditions also apply:

The project shall be represented by at least one Project Participant at the programme conferences, seminars and network meetings arranged within the

⁸Our current terms and conditions can be found on our website, together with a guide to understanding and complying with the terms and conditions. <https://www.vinnova.se/en/apply-for-funding/rules-for-our-funding/terms-and-conditions-for-our-funding/>

programme Next-generation Biologics. The cost of such participation is eligible for funding.

Supplementary specific terms and conditions may be decided on for individual projects.

If you do not fulfil our terms and conditions, you may be obliged to repay the grant. This applies also if you have been awarded a grant wrongly, or in too high an amount.

9 How to apply

To apply for a grant, first choose whether you want to apply for a grant for at most 5 million SEK, or if you want to apply for a larger grant – up to 10 million SEK – with an increased requirement for co-funding. You can find both options on our website. Select one, and log into our application service, Vinnova's eServices Portal, where you fill in a web-based form.

Here you shall also upload the following appendices⁹:

Project description

The project description has a maximum size of 10 single-column A4 pages in portrait orientation, font size 12, black text. References to websites and similar information will not be taken into account.

CV appendix

The CV appendix shall include CVs for the project manager, one representative for each project participant and other key persons in the project. Each CV must cover a maximum of 1 A4 page, font size 12, black text.

All project participants must be included in the CV appendix, including project participants that are not applying for a grant.

Budget

The budgets of all project participants must be reported, including the budgets of project participants that are not applying for a grant.

⁹Templates for the appendices can be found on our website:

<https://www.vinnova.se/e/proteinforskning-och-processutveckling-for-2018-02527/proteinforskning-och-processutveckling-for-biologiska-lakemedel--mindre-projekt/>
<https://www.vinnova.se/en/e/proteinforskning-och-processutveckling-for-2018-02527/proteinforskning-och-processutveckling-for-biologiska-lakemedel-storre-projekt/>



The size of the appendices must not exceed the size stated above, and no further appendices may be attached.

Once the call deadline has passed, applications may only be supplemented at our request.

10 Who can read the application?

Applications submitted to us become public documents, but we do not disclose information about individual business or operational circumstances, inventions and research results if it can be assumed that any individual will suffer if the information is disclosed.

Appendix 1

The programme Next-generation Biologics

Background

The Swedish Government has mandated Vinnova and the Swedish Research Council to jointly develop a national programme for protein research, method development and production of biologics.

The research programme is part of the Government's strategic investment in life science, which overall shall contribute to improved health, to addressing societal challenges, to strengthening Sweden's position as a leading country within research and development, and to increasing Sweden's competitiveness in an international perspective.

The programme will run for eight years (2016–2023), and has a budget of 320 million SEK. Private co-funding corresponding to an indicative 25 per cent shall be included in the programme.

To date, one call for project proposals – Development and production of biologics – with two application opportunities (2016 and 2017), and one call for centres – Centre for Development and Production of Biologics – with one application opportunity (2017) have been issued within the programme.

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

Impact goals of the programme

- to build up a strong knowledge base within biologics
- to reinforce the opportunities of health and medical care to receive new biologics
- to increase Sweden's attractiveness as a collaboration partner and for investments in research, development and innovation for next-generation biologics
- to increase the competitiveness of companies in Sweden in an international perspective
- to increase the collaboration between academia, industry and health and medical care
- to develop more efficient methods of production for next-generation biologics

Logic Chart

Figure 1.

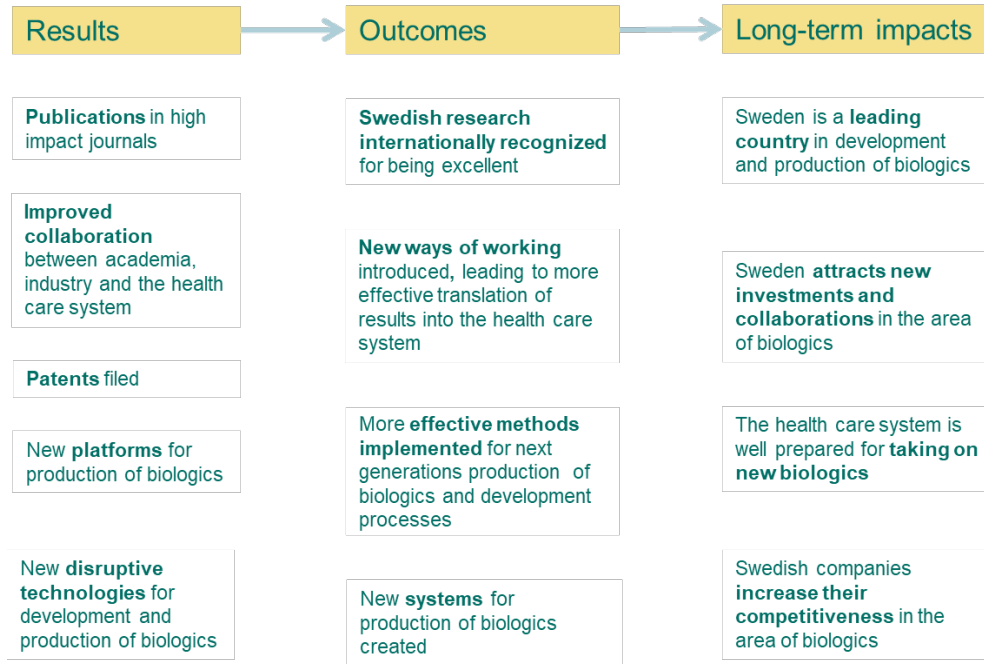


Figure 1. The image illustrates the logic chart for the Next-generation Biologics programme. Results are generated during the programme period and soon after the end of the programme. Short-term effects are expected within approximately five years, and long-term effects after ten years from the end of the programme.