

Centre for 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 shared responsibility to establish a national programme for protein research, method development and production of biologics.

Vinnova and the Swedish Research Council invite consortia consisting of parties from different sectors, such as academia (including research institutes) industry and optionally the health care sector to send in applications for funding of centres

This call “**Centre for development and production of biologics**” aims to create strong research, development and innovation milieus and to increase the cooperation between academia, industry and the health care sector in order to develop Sweden into a leading country in the field.

The purpose of supporting the development of new centres is for industry, academia and society at large to gain access to knowledge and expertise that meet existing needs. The needs can be of different sorts and therefore different competences regarding all aspects of development and production of biologics should be available such as regulatory, clinical, health economy, engineering and also competence for performing road map analyses.

Proposals should address important aspects of the development and production of biologics. All proposals should aim at solutions with economical, societal and environmentally positive impact.

Last application date is 28th of March 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 shared responsibility to establish a national programme for protein research, method development and production of biologics. Within the program at least one centre shall get funded. More information about the programme is found in Annex 1.

3 Call for proposals: centres for development and production of biologics

3.1 Who can apply

The call for proposals is intended for consortia, consisting of **several parties** that should come **from different sectors**: academia (including research institutes) and industry and optionally the healthcare sector. A party from academia needs to be designated main applicant (coordinator). See Formal application requirements in section 5.

All centre parties must be actively involved in the design and implementation of the project results and share the associated risks and outcomes. (For more information on the role of the centre parties, see Vinnova's general terms and conditions). Co-funding of 25% from the industry and 25% from academia together with the health care sector (including research institutes) is required. Thus, Vinnova's part of the budget will maximum be 50%.

International parties are welcome to participate in the proposed centre, but cannot receive funding.

3.2 Scope of the call

3.2.1 Centre characteristics

A centre must have a centre director (project manager for the centre's activities) and a centre board of directors. The centre's board shall actively promote the interests of the centre and to have authority over the direction of research. At least half of the members of the centre's board shall come from the private sector or non-academic public activities, including the chair of the board. The board must have a balance of genders, at least a 40/60% balance.

A well-functioning centre requires active leadership, both from the centre's director and its board, and active cooperation between the relevant stakeholders within industry, academia (including research institutes) and the health care sector.

A centre should consist of parties with mutual interest in the theme for the centre activities. The number of parties can differ from proposal to proposal. The most important thing is to achieve a critical mass so that many interactions and a lot of exchange of information can take place in order to come up with new ideas for innovations.

3.2.2 The proposal

Proposals should address important themes of the development and production of biologics. All steps along the value chain will be difficult to include in one proposal and this is not the intention with this call either. Focusing on parts of the value chain where certain challenges exist and where needs and interest have been expressed by the parties can be the theme for a proposal. Applicant should therefore state and explain the importance of the themes chosen. It is expected that knowledge about most of the aspects on development and production of biologics should be available at the centre e.g. knowledge on the regulatory landscape, clinical relevance and engineering challenges. Also international outreach and road map analysis can be important components in a centre. The centre shall also act as an information/knowledge bank where different actors can seek knowledge and recommendations in specific questions.

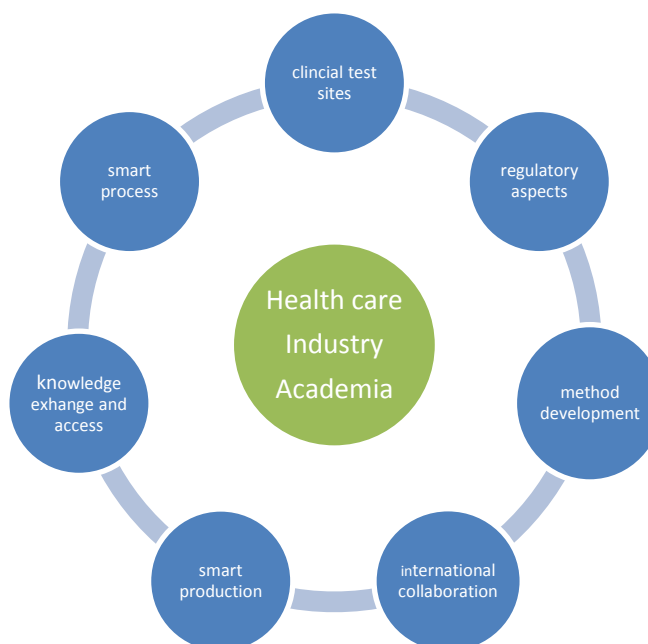


Figure 1. Schematic picture on different aspects that can be involved in a centre proposal

The theme for the centre activities should be of interest for all parties and it is expected that all parties can contribute to the majority of projects in the centre i.e. Vinnova and the Swedish research council expect multi-lateral projects rather than bi-lateral projects included in the plan for the centre. The operational plan is also expected to include projects at different TRLs (technology readiness levels), some at more basic research level and others taking on challenges and needs at other levels along the value chain. All proposals should aim at solutions with economical, societal and environmentally positive impact and thus be able to contribute to a sustainable development.

Gender equality is an important aspect to consider when proposing a project within the centre. Women and men should have the same opportunities to gain from the grant. Both men and women should take part in the centre activities, as well as in the decision-making in the project team. The foreseen centre results should contribute to increased gender equality.

3.3 Goals and expected results

The goal of this call is to create new internationally-competitive centres conducting *cooperative needs-driven top-quality research* within the field of biologics. Innovations often arise through interaction among various stakeholders (industry, suppliers, customers, research institutes, academia and the health care sector) who all contribute with their different perspectives to a problem. A well-performing centre will stimulate interactions between several parties on all levels.

3.4 Expected results

Expected results contributing to the goal of this call:

- Creation of strong research, development and innovation milieus
- Established collaboration and networks between academia, industry and optionally the health care
- New disruptive technologies for method and process development and production of biologics
- A competence resource where actors can seek knowledge in the field of development and production of biologics
- Established links to key international actors and international milieus

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 centre description, a CV appendix on key personnel, budget and Letter of intents signed by an authorized signatory from all parties should be attached to the application. The attachments shall be in PDF format.

The CV appendix must be written in the specific template for the application and include CVs of the centre manager, a representative of each of the centre parties, and other key members of the management team. Each CV should be no longer than 1 A4 page, written in 12 pt, black font.

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

The budget must be written in the specific template for the application including:

- a. A cost budget divided on work packages/larger projects, the parties' contributions should be included.
- b. Revenue budget including cash and in-kind financing from all parties.

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

References to information on websites etc. will not be considered.

The centre description should be written in the specific template and should be maximum **25** A4 pages with size 12 text and have the following main headings (sub-headings are only guidelines and do not need to be answered specifically).

1. Vision, strategy and goals

- a. Describe your vision and your strategy for achieving it, expressed in the medium-term (6 years) and long-term (> 10 years) for the centre.
- b. Clarify how the centre contributes to increased growth of industry and the development of the health care sector.
- c. Describe the needs and benefits for the involved stakeholders from the private and public sectors who participate in the centre.
- d. Describe the conditions necessary for the centre to remain an internationally attractive and competitive research environment.
- e. Present the expected results.

2. Existing activities in the field

- a. Describe the work by the parties in the centre, provide examples of relevant publications, patents, etc..
- b. Describe the competition i.e. the proposed centre in relation to international initiatives in the field of research.
- c. Describe possible international collaborations.
- d. Describe how the centre can supplement and strengthen activities already ongoing in the research field.

3. Parties

- a. Present the participating parties included in the centre and their collective competences, profiles and resources in relation to the centre's operations.
- b. Describe the proposed centre in relation to **the main applicant's** long-term research strategy and innovation environment.
- c. All involved parties should specify their commitments in the form of co-financing and reasons for participating in the centre. This is to be done through separate letter of intent (attached as annexes).
- d. Describe how the composition of competences reflects the current areas of operations and how it offers the potential for realizing the centre's vision and goals.

4. The structure of the centre

- a. Describe the environment's geographical focus. If the centre consists of multiple nodes, describe how you will manage the nodes and achieve a sufficient critical mass within the centre to achieve an optimal research and innovation environment.
- b. Describe the proposed organizational structure.
- c. Describe the interaction between the centre's various actors and how the various actors can complement each other to achieve a dynamic research and innovation environment that offers the potential for innovation.

- d. Describe how the centre will develop international links, e.g. to key actors, to milieus in other countries that complement your centre, to new international collaborations.

5. Implementation and outcomes

- a. Describe the experiences and competences important for the prospective centre director and the rest of the management's ability to lead a centre.
- b. Describe the structure of decision-making at the centre.
- c. Describe how leadership will be implemented to the entire organization and for sub processes.
- d. Describe how you plan to follow-up your work and measure impacts.
- e. Describe the preliminary project portfolio, including descriptions of the project proposals that you want to implement within the centre.
- f. Report the timetable and milestones – what do you want to achieve by different points in time.
- g. Describe the long-term potential for maintaining the operations, structures and networks created within the centre.

5 Formal application requirements

To qualify for an assessment, in accordance with the criteria stated in section 8.2 below, the following requirements must be satisfied:

- A party from academia (including research institute) needs to be designated main applicant (coordinator).
- The centre parties must be legal entities
- Letters of intent from all the participating parties are to accompany the application
- The application must include all mandatory attachments
- The attachments should be correctly completed in the mandatory templates for this call
- The budget should include 25% private co-funding from industry and 25% from academia together with the health care sector
- The board should have a gender balance of at least 40/60%

Please note that any additional attachments (more than the requested CV, budget and LOI) that result in a centre description exceeding the maximum 25 pages allowed automatically means that the application is disqualified.

6 Budget and conditions for funding

6.1 Budget

The budget for this call is SEK 96 million. Centre grant period is up to 6 years and maximum funding per year is SEK 8 million.

6.2 Conditions for funding

Eligible costs are determined based on the nature and content of the centre 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 and can be found on Vinnova's homepage.

Participants from academia, research institutes and healthcare may receive up to 75% of their total budget in the centre, provided that the centre is part of their non-economic activities.²

Industry will not receive any funding.

A party receiving funding cannot distribute it to another party.

Funding will not be given for any activities done before start of the centre.

7 Schedule

The following dates apply to the call:

Call opens: 14th of November 2016

Last application date: 28th of March 2017, 14:00 CET.

Interviews: May 2017 (only selected proposals; see section 8.1)

Final decision date: 15 June 2017.

Date for centre start: Q1 2018.

² 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.

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, the health care sector, industry and also centre specialists. Interviews will be performed with the collaborating parties of the proposal receiving the highest ranking from the international panel. Vinnova will after discussion with the Swedish Research Council make the final decision regarding funding of selected proposals, based on the interviews and 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 proposal 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 proposal in relation to the goal and expected results of the call
- Innovativeness and novelty of the centre idea
- Scientific quality of the research hypotheses and methodology
- Potential of the proposal to contribute to increased competitiveness of Swedish industry in the actual field
- Potential of the proposal to contribute to improved health care
- Economically, environmental and societal, including the equal opportunities perspective, impact of the centre and its foreseen results
- Potential to establish relevant international links

Feasibility

- Collaboration between centre parties and other stakeholders of significance to the centre
- Approaches chosen to reach the centre goals and the goals of the call.

- Credibility of the budget and the centre operational plan, including timeline, milestones and activities, in relation to what is to be achieved (vision and goals)
- Ethical considerations
- Measures taken to achieve an economically, environmental and societal positive impact of the centre and its foreseen results
- Plan for implementation and utilization of the results, including IPR-strategy

Participants

- Overall managerial skills and experiences of the members of the centre; especially the Centre Manager and the Chairman of the Board but also other persons in leading positions
- Relevant competence in the team, for reaching the goals of the centre and of this call.
- Involvement of the project parties (actors) in the centre, with working hours and other resources
- Gender balance in the centre, in the planned projects as well as in the centre management and board
- Involvement of users and recipients along the value chain

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, centre 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.

Special terms and conditions will be used for the approved centres, and these will be amended to the agreement in connection with the decision. The special conditions will include that a centre is to have a centre director (project manager for the centre's activities) and a centre board of directors. The chairman of the board should have an industrial affiliation or an affiliation from the public sector. At least 50% of the board members should come from the industry or the public sector. Special terms and conditions will also state that all researchers from academia (including research institutes) participating in the centre should sign-off their rights to their results to the centre.

10 Agreement

A centre's operations are to be subject to an agreement between all the parties in the proposed centre. The agreement will regulate the rights and obligations. The parties may use the draft agreement available on VINNOVA's website.

For a small company, it can be difficult to commit to a 6-year contract. For this reason, VINNOVA encourages applicants to develop contracts and governance models that enable small companies to participate in the centre for limited periods.

11 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".

12 Contact

11.1 Contact persons for this call

Mats Jarekrans
mats.jarekrans@vinnova.se
+4684733185

Margareta Danielsson
margareta.danielsson@vinnova.se
+4684733152



Johanna Ulfvarson
johanna.ulfvarson@vinnova.se
+4684733218

Karin Tegerstedt
Karin.Tegerstedt@vr.se
+46854644257

11.2 Contact for administrative questions

Karin Sundbeck
karin.sundbeck@vinnova.se
+4684733226

11.3 Contact for questions on the application service

Vinnova's IT-support, helpdesk@vinnova.se ; + 46 (0)8 473 32 99

ANNEX 1

The programme Next-generation Biologics

This research programme is part of the Government's strategic investment in the life sciences that aims to improve health, meet societal challenges and strengthen Sweden's competitiveness in an international context. The purpose of the programme is to develop Sweden into a leading country in development and production of biologics.

The core programme will extend over a period of eight years (2016 – 2023) and has a budget of SEK 320 million. In addition, a private co-funding corresponding to a minimum of 25 percent is expected. One part of the programme should include funding of at least one centre and the goal is to create strong research, development and innovation milieus. The purpose of supporting the development of new centres is for industry, universities and society at large to gain access to knowledge and expertise that meet existing needs

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, antibodies, vaccines, blood/plasma-derived products, macro-molecules, non-recombinant culture-derived proteins, and cultured cells and tissues.

Impact goals of the programme

The impact goals of the programme are:

- To create new knowledge on next-generation biologics
- To make Sweden attractive for cooperation and investments in research and development
- To increase competitiveness of Swedish industry in an international perspective
- To promote and develop cooperation between academia (including research institutes), industry and healthcare
- To support the development of efficient methods for production of next-generation biologics