CLOSED CALL 15 January - 18 February 2020

Research environment grant within clinical therapy research

Outline application.

The purpose of the grant is to provide support for clinical therapy studies that are justified by the needs of health and medical care and are expected to lead to patient and societal benefit within a relatively short period of time.

Therapy studies refers to both intervention and observation studies. Areas such as prevention, diagnostics, follow-up, implementation, care and rehabilitation are also included. The grant aims to enable a constellation of researchers within regions and academia to work towards a common research goal.

The Swedish Research Council rewards research of the highest scientific quality in national competition.

Support form: Research environment and collaboration support

Subject area: Clinical Therapy Research

Focus: Clinical therapy research

Applicant: Individual researcher

Participating researchers: No participating researchers may be invited to join the project outline

Grant period: 4 years

Grant amount: Minimum 1 000 000 SEK per year, maximum 20 000 000 SEK over 4 years

Start of grant period: January 2021

Application period:
Project outline: 15 January 2020 (14.00/2 p.m.) – 18 February 2020 (14.00/2 p.m.)
Full application: 10 June 2020 (14.00/2 p.m.) – 25 August 2020 (14.00/2 p.m.)

Publication of grant award: No later than the beginning of December 2020

Please note:

- As from 2020, you must explain in your research plan how your stated activity level is suited to the implementation of the research project.
- You must describe whether sex and gender perspectives are relevant for your research and, if so, in which way you will use such perspectives, or why you choose not to do so. How sex and gender perspectives are managed in the research project will form part of the assessment of scientific quality. Read more under the heading “Research description” and on our website.
- You will need to have a data management plan for data generated within the research we award funds for. You must not send the plan to us, but according to our general grant terms and conditions, your administrating organisation must confirm that a data management plan will be in place when you start your project or equivalent, and also that the plan will be maintained.

PREVIOUSLY APPROVED GRANTS

Read more about grants awarded in previous years

Specific instructions for the call

In addition to reading call text, you also need to consult our Guide for applicants.

Application procedure

Applications for research environment grants within clinical therapy research are submitted in a two-step process. First, you as applicant must submit an project outline for evaluation. Applicants whose project outlines are approved shall then submit a full application.

Project outline

In the project outline, the emphasis shall be on the research question and the expected patient benefit and societal benefit. The study design, statistical method and materials shall be described sufficiently clearly to allow the feasibility of the project idea to be evaluated. Please note that there must not be any major discrepancies between the outline and full applications in terms of the research plan or budget.

The Swedish Research Council will make a decision on the project outlines in May 2020. If your project outline is accepted, you will also receive notice via email, including instructions for how to submit a full application. Relevant information from the project outline will automatically be transferred to your draft for the full application.

Full application

The call for full applications will be open from 10 June to 25 August 2020.

Compared to the project outline, the full application must include the following:

- a more comprehensive research plan, including specific intermediate objectives to be reported back and evaluated on an ongoing basis
- more detailed descriptions of “Call-specific information” (see below)
- a full budget description
- a full list of publications
- the participating researchers (minimum 3 and maximum 10), plus their CV details and publications

Contrary to what applies to the project outline, the full application must also be signed by an authorised representative of the administrating organisation within 7 calendar days from the deadline for applications.

Here you can find links to information and support that can make the planning and implementation of your research project easier:

The collaboration Clinical Studies Sweden consists of six regional nodes, one in each healthcare region. The nodes can provide contacts with relevant regional resources, such as research units, quality register centres, biobanks and cancer centres. The nodes can also give you support in your work in areas such as

- study protocols, permit applications, data management and statistics
- infrastructures for implementation (such as FITH-Phase-IV and specialist units within primary care and paediatrics)
- training within clinical research methodology (such as GCP and statistics)
- expertise relating to statistics, epidemiology and health economics

You can find more information about the nodes at kliniskastudier.se. This also includes a step-by-step guide that describes the study process and what you need to consider when conducting a clinical study.

At Registerforskning.se there is information for those who are planning to use register data in research projects. Here you can also find the metadata tool RUT (Register Utiliser Tool), which offers researchers detailed information at metadata level about the variables used in Swedish registers and biobank sample collections.

Requirements for applicants

The following requirements must be fulfilled in order for you to be eligible to apply for the grant. We carry out checks, and reject applications that do not fulfil the requirements.

Focus

The research shall be clinical-based and assumes access to healthcare structures and resources. Projects of relevance for this call are clinical therapy studies, aimed at producing reliable and implementable results that may be of benefit to patients and society within a relatively short period of time (within 2–10 years after completion of the project). National collaboration is a requirement, and the main part of the research in the application shall be conducted in Sweden. For this year's call, one portion of the funds set aside shall be allocated to projects answering to identified and prioritised needs for knowledge, which is done in consultation with the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU).

Link to SBU's interpretation and evaluation of a knowledge gap.

Applicant

The applicant for a research environment grant within clinical therapy research shall be an individual researcher. You shall be the project leader and have scientific responsibility for the project. The time you set aside for the project (your activity level, that is the percentage of a full-time equivalent) must be suited to the task and its implementation throughout the grant period.

You must hold a Swedish doctoral degree or an equivalent foreign degree, awarded no later than the deadline for this call. The degree award date we use is the date you fulfilled all the requirements for a doctoral degree, such as mandatory courses, oral defence and an approved doctoral thesis. For applicants with Swedish doctoral degrees, the award date listed in Ladok applies.

At the time of application and throughout the grant period, you must hold a clinical position in Sweden, that is, be employed and carry out clinical work e.g. as a physician, nurse, dentist or physiotherapist. The scope of this employment must correspond to a minimum of 20 per cent of a full-time equivalent. You must describe the clinical work in your application (see instructions under "Clinical employment" below).

Grants from the Swedish Research Council shall be administered by a Swedish university or HEI or another Swedish public organisation that fulfils our criteria for administrating organisations. Your organisation must therefore be approved as an administrating organisation for you to apply.

If you are awarded a grant, you must be employed by the administrating organisation at the start of and throughout the grant period and any additional availability period, unless the Swedish Research Council approves an exception from this requirement. The employment must equal at least 20 per cent of a full-time equivalent. You do not have to be employed by the administrating organisation at the time of applying.

Number of applications and previous grants

What grants may I apply for simultaneously from the Swedish Research Council?

You may apply for this grant at the same time as you apply for a project grant, but if your application for the project grant forms part of this grant application, this fact will be considered during the overall weighted assessment of the resource requirement.

You may only submit, that is be the applicant for, one research environment grant under this call. On the other hand, you may be included as a participating researcher in several applications under the call.

You may not apply for a research environment grant under any other of the Swedish Research Council's calls, but you may be included as a participating researcher in such applications. Other restrictions on the grants you may apply for during the same year are shown in the table below.

Table: Grants you may apply for simultaneously

What requirements apply if I already have a grant from the Swedish Research Council?

There are certain restrictions if you are the project leader of an ongoing grant, that is to say where the grant period (payment period from the Swedish Research Council) overlaps the grant period of the grant the application relates to. Please note that the availability period, that is to say the time during which you have the right to use your grant, is normally longer than the grant period. Information about the criteria for your previous grant can be found in the “Approval of Conditions” you received from the Swedish Research Council.

You may apply for a research environment grant if you are the project leader for an ongoing research project grant (however not if this is within the area of clinical therapy research) or career grant. A prerequisite for the application to be successful is that the grant awarded is not part of the application for a research environment grant, but on the other hand, the grant awarded may complement the application.

You may not apply for this grant if you are the project leader for an ongoing research environment grant.

If you have a distinguished professor grant with a grant period that overlaps the grant period for this call, or are a researcher recruited through the Swedish Research Council’s international recruitment call, you may not apply for a research environment grant. On the other hand, you may participate in an application for a research environment grant.

The table below shows information and other restrictions on the grants you may apply for if you already have an ongoing grant.

Table: Grants you may apply for if you have an ongoing grant

Note: If you have been the project leader for previous grants from the Swedish Research Council that have ended, final financial reports for all of these must have been submitted within the permitted time frame in order for you to apply for a new grant. Please contact your administrating organisation if you are unsure whether all your final reports have been submitted.

What applies for applications to or grants from other funding bodies?

If your application to the Swedish Research Council relates to the same project idea as a grant you have already been awarded by, or are applying for to another funding body, please describe this.

Participating researchers

No participating researchers may be invited in this project outline. Please describe any collaborating partners and their roles under the heading “National collaboration” (see instructions under “Call-specific information” below).

Costs and grant amounts

You can apply for a grant for all types of project-related costs, such as

- salaries (including your own salary), however no more than corresponding to the person’s activity level in the project
- premises
- running costs (such as consumables, travel including stays at research facilities, publication costs and minor equipment)
- depreciation costs

Grants must not be used for scholarships. If a doctoral student participates, project funds may not be paid out as salary during teaching or other departmental duties. Only additional costs in conjunction with clinical studies are covered by the grant, not other medical care costs.

The minimum amount you may apply for is 1 000 000 SEK per year, including indirect costs. The maximum amount you may apply for is 20 000 000 SEK over 4 years.

The Swedish Research Council assumes that the administrating organisation will cover any costs in excess of the amount received.

Grant period

The grant period is 4 years, starting in January 2021. The first payment will be made during January 2021 at the earliest.

National collaboration

National collaboration between a higher education institution and a number of regions is a requirement for applications for this grant. This is to ensure the studies and their results have good impact. The requirement for national collaboration may be fulfilled either through active patient recruitment in several regions, or through collaborators in several regions (for example if patient recruitment is not done actively). The collaboration shall be based on an actual need for interaction. The need may, for example, consist of ensuring sufficiently large patient numbers. Other needs for collaboration may related to access to high-quality data sources, equipment or specialist competency within several disciplines. Collaboration with companies in the medical sector that are active in Sweden should also be taken into account.

The collaboration must include a minimum of 4 regions, unless there are special circumstances. Such special circumstances may be that the application relates to national highly specialised care, or to diseases that are relevant to only a few regions. If the requirement for at least 4 regions cannot be fulfilled, the applicant must justify this in the application, and this justification will be weighted into the assessment whether the application fulfils the requirement for national collaboration.

Reporting and follow-up

If you are awarded a grant, you must submit a follow-up report to the Swedish Research Council no later than 1 year after the start of the grant period and yearly afterwards. The purpose of the follow-up is to ensure that the project is running as planned, for example that the time plan is kept to, that patients are recruited at the expected rate, and that the quality of the data material is sufficiently high. Depending on whether the result corresponds to the prerequisites on which the grant was awarded, the Swedish Research Council may decide not to extent the grant, or to review the grant amount after the second annual follow-up report. The Swedish Research Council will also request information to ensure ethical approval has been given for the planned study, and may terminate the grant or change the grant amount if this is not fulfilled.

What must the application contain?

Please refer to the application form in Prisma in parallel with reading the instructions below, which describe the call-specific content of the application. More information on what to do in practical terms is available in our Guide for applicants .

Language

Foreign experts are involved in the scientific assessment of the applications. To ensure fair and equitable assessment and efficient processing, please therefore complete your application in *English*.

Sections of the application

The application form includes the following tabs:

- Descriptive information
- Research description
- Call-specific information
- Budget and research resources
- Publications
- Administrating organisation
- Review panels
- Participants (only administrators in this call)
- CV

The information we request under each tab is described below.

Descriptive information

In the abstract, please briefly describe the following:

- what is to be done: purpose and aim
- how the research problem will be studied in a summary project design, including patient sample, choice of variables, data collection and analysis methods, and time plan. For intervention studies: please use PICO (population/intervention/control/outcome)
- what the direct patient benefit is from the planned research

The abstract shall provide a summary picture of the purpose and implementation of the research. Please use wording to ensure persons with another subject specialisation can understand the information.

The description may cover a maximum of 1 500 characters including blank spaces. This is approximately 1/3 A4 page in Arial, font size 11, single line spacing.

Describe the project in such a way that a person who is not familiar with the subject can understand it. Describe what is to be done, and why. Explain also in what way the new knowledge may be important.

The popular science description is an important tool when we inform about the research funded by the Swedish Research Council. If we grant your application, we reserve the right to use the description for information purposes.

The description may cover a maximum of 4 000 characters including blank spaces. This is approximately 1 A4 page in Arial, font size 11, single line spacing.

Note: The popular science description must be written in Swedish, unlike the rest of the application.

Research description

Describe the ethical issues raised by your project or corresponding. You must also describe how you plan to address ethical dilemmas that may arise. Please justify why the research should be carried out against the background of the ethical issues you have identified. How do your research questions and expected results measure up in relation to the ethical issues? Please also state whether the research involves any handling of personal data, or experiments on human subjects. If no ethical issues are raised, please justify this.

The description may cover a maximum of 4 000 characters including blank spaces (approximately 1 A4 page in Arial, font size 11, single line spacing).

Please state whether sex and gender perspectives are applicable in your planned research, and justify your decision. Please note that we are not asking for information about the composition of the research team (men/women). Read more about sex and gender perspectives in research content.

The following applies:

- If you answer “Yes”: Justify your answer, and describe also how you take account of sex and gender perspectives in the research plan. If you have stated that sex and gender perspectives are applicable, but still choose not to include them in your research plan, you will need to justify this here.
- If you answer “No”: Please justify your answer.

- The research plan shall be forward-looking and consist of a brief but complete description of the research task. It shall cover a maximum of 4 page-numbered A4 pages in Arial, font size 11, single line spacing and 2.5 cm margins, including references and any images.

The research plan must include the following headings and information, listed in the following order:

- **Purpose and aims:** State the overall purpose and specific goals of the research project, and provide brief background information and justification for the project. Specify the main research question and the primary endpoint, which must be clinically relevant.
- **Survey of the field:** Summarise briefly the current clinical practice and evidence-based clinical knowledge about the research field. List any systematic reviews, national and international guidelines and identify gaps in knowledge that justify more research being needed (maximum 1/2 A4 page). Please exclude any review of pre-clinical and technical data and of the burden of disease.
- **Study design:** Describe the design of each sub-study/question and justify why the proposed study design is the most suitable one for answering the question. For intervention studies, all therapies studied and compared shall be described in detail in terms of factors such as type(s) of therapy, dosage, follow-up periods, evaluation, etc. For intervention studies, please use PICO (population/intervention/control/outcome). For controlled cross-section studies, the therapy given to the control group shall also be described. Stating the standard therapy is not sufficient. Any differences between the therapy procedures of the participating clinics shall be clearly described. For cohort/observation studies, any confounders shall be identified and the treatment of these described. For cross-over studies, where the patient is their own control, the planning of the various therapy periods shall be described, and also how the risk of “carry-over” effect, etc., is taken into account. For longitudinal studies, the choice of repeat follow-up occasions shall be justified. It shall be clearly shown which follow-up occasion is related to the main outcome of the study. Equally detailed description of the data collection shall be provided for register-based studies when patient data is collected from one or several different registers. All outcomes shall be stated. For subjectively-based outcomes, such as PROMs (patient reported outcome measures), it is not sufficient to state the name of the questionnaires. It is important to take into account the fact that register data for the same outcome may have been registered using different types of measuring instruments/assessment forms, which result in non-comparable data.

The study design must include the following information under separate headings, listed in the following order:

- **Research questions:** Structure the purpose of the research into questions. What is to be studied, and in whom? Specify the primary outcome variable of each research question and the secondary outcome variables involved as well. In therapy effect studies, the effect variable (such as target value or percentage change to the primary outcome) shall also be specified. Justify any use of a surrogate endpoint.
- **Variables and measures:** Describe how each variable (primary, secondary, background or explanatory) will be measured and recorded (for example binary, categorical, ordered categorical, continuous or transformed). Uni- and multi-dimensional variables, such as pain, ability, severity, quality of life are commonly assessed on rating scales in various questionnaires. In such cases, the dimensions/variables used shall be stated, and also the type of response alternative (such as numerical, verbal categories, VAS), and the way in which the data collected is used shall be stated. Please include appropriate references to any questionnaires/rating scales.
- **Material: Patient selection – Population, sample** Describe briefly the characteristics of the study population, and state inclusion and exclusion criteria for patient selection in the study/sub-studies. Describe also how the participating clinics contribute to the patient selection, and how any differences between clinics that could affect the study will be handled. For register studies, any potential risk of systematic under or over-registration of patient groups shall be taken into account when defining inclusion and exclusion criteria. For randomising: Describe the randomisation approach, and specify who is responsible for the randomisation. Please also state for whom (patient, therapist, evaluator) the randomising is blind, and justify any exceptions.
- **Estimated sample size and power:** Explain and justify the smallest difference in treatment effect/primary outcome variable between control and treatment (or equivalent) to be clinically important to detect and estimate the sample size of the study/sub-studies thereafter. Calculate the power of the study for the planned sample size, taking account of estimated drop-outs, if possible based on previous own studies or studies by others. The distribution of patients across the participating clinics and as applicable any planned multiple statistical tests and/or interim analysis shall also be taken into account in dimensioning. Describe also, where applicable, how the patient compliance with the study will be monitored and/or taken into account.
- **Statistical methods:** Each research question should be linked to specified statistical methods that are based on the specified variable selection, the method for data collection and planned management of data for statistical description. The choice of statistical analysis (hypothesis testing)

and/or modelling, quality assurance or similar shall be described. Verify that the proposed statistical approach is relevant for the question asked, and for the characteristics of the data material. It is not enough to use general concepts such as descriptive statistics, parametric and non-parametric methods or standard methods for analysis. Please note that the normal distribution could be a possible probability distribution for symmetric quantitative data, such as laboratory data, but never for data from assessments in questionnaires. Examples of other method issues that may have to be considered: How will dependent data be handled, for example within the group and/or between groups? Which statistical methods are planned for complex data from questionnaires and other subjective assessments, which are expected to generate ordered category data? How will longitudinal data and drop-outs be handled? What are the criteria for any interim analyses? Is there reason to adjust for multiple testing? Specify who is responsible for the statistical analysis plan.

- **Time plan:** Describe briefly the time plan for the study during the grant period.
- **References:** Include references, but limit them to maximum 1/2 A4 page.
- **Project organisation:** Describe the project organisation and the participating clinics/hospitals. Clarify the contributions of yourself and any other researchers and/or key persons to the implementation of the project, including a description of competences and roles in the project. Explain in particular how the time allocated by you (that is, your activity level) as project leader is suitable for the task, including the relationship with your other research undertakings. Describe how representatives of users/patients have participated in the trial planning and how they are involved in the various subsidiary steps, such as continuation planning, implementation and evaluation.

Provide the following information also. If the heading is not relevant to your application, please state this.

- **Other applications or grants:** If you are applying for or intend to apply for other grants from the Swedish Research Council, please clarify the relationship between the projects. This applies also if you are receiving ongoing grants from the Swedish Research Council with grant periods that wholly or partly overlap with the grant you are now applying for. You should also justify why you are submitting one or several further applications. Describe also the relationship with other applications to or grants from other funding bodies for the same project idea (from you or another researcher).

If you are or have been the project leader for a research environment grant within the area of clinical therapy research, where the Swedish Research Council's payment *period* for the funds awarded ends no later than December 2020, you must submit a preliminary scientific report, including a financial account. The report shall describe how the project has proceeded.

Please state the project name, registration number, grant amount and grant period (that is the payment period from the Swedish Research Council; the remaining availability period shall not be included) for the previous project.

Please describe the following:

- the scientific results achieved to date within the previously awarded project
- the relationship between the previously awarded project and the planned project
- the total research resources available for the implementation of the project during the reported grant period. State the grant type, funding body, holder and amounts involved (including the previously awarded grant from the Swedish Research Council).

The description may cover a maximum of 8 000 characters including blank spaces. This is approximately 2 A4 pages in Arial, font size 11.

Call-specific information

Describe how the project results – in terms of direct patient benefit – are expected to come into practical clinical use within a relatively short period of time (within 2–10 years of the completion of the project). Specify and explain in which way the results are being requested by patients and other stakeholders. Factors such as prevalence, the severity of the disease and the cost to society shall be weighed into the description of clinical benefit.

Describe how the project results may contribute to better use of resources within health and medical care, and any potential gain for society as a whole. Discuss the possible health economics considerations that the project results may lead to.

The description may cover a maximum of 1 500 characters including blank spaces. This is approximately 1/3 A4 page in Arial, font size 11, single line spacing.

User participation is necessary to ensure that user viewpoints, and also expressed wishes and needs, are taken into account when selecting the primary outcome variables for the study. Describe how representatives of users/patients have participated in the trial planning and the choice of outcome variables. Describe also how users/patients are involved in the various subsidiary steps of the study/project, such as continuation planning, implementation and evaluation. In addition to patient groups, the concept of user participation shall include patient organisations, relatives and others who may benefit from the results of the research. If you or anyone else has prioritised among existing gaps in knowledge within the area with the help of user participation, please describe this.

The description may cover a maximum of 1 500 characters including blank spaces. This is approximately 1/3 A4 page in Arial, font size 11, single line spacing.

Describe how the result of the proposed research can be utilised through being implemented in health and medical care. Include a clear level structure and a time plan for implementation. State also the clinical effect goals that shall be used to measure implementation.

The description may cover a maximum of 1 500 characters including blank spaces. This is approximately 1/3 A4 page in Arial, font size 11, single line spacing.

State which Swedish regions, other researchers and companies will collaborate in the project. Describe also any collaboration with foreign equivalents. Describe the positive effects the collaboration may lead to. These may relate to factors such as ensuring a sufficiently large patient sample, access to high-quality data sources, equipment or specialist competency within several disciplines.

If the requirement for at least 4 collaborating regions is not fulfilled, please justify this.

The description may cover a maximum of 1 500 characters including blank spaces. This is approximately 1/3 A4 page in Arial, font size 11, single line spacing.

Please state the number of Swedish regions that are contributing to patient recruitment and the names of these regions in the separate text fields. Please make sure the number of regions corresponds to the number of names selected for participating regions.

Describe in what way you fulfil the requirement for holding a clinical employment in Sweden (please refer to the section “Requirement for applicants”), and what your clinical employment involves.

The description may cover a maximum of 750 characters including blank spaces in Arial, font size 11.

Budget and research resources

The maximum amount you may apply for is 20 million SEK. The grant amount includes cover of indirect costs.

Please contact your administrating organisation if you have any questions about what constitutes indirect and direct costs.

Please state the amount per year applied for. The amount applied for will be shown under “Operating costs” in the table summarising the overall cost of the project.

Briefly justify each cost applied for in your budget.

You must clearly show the costs for which you are applying for funding from the Swedish Research Council, and the costs that may be covered via other grants awarded. Only additional costs in conjunction with clinical studies are covered by the grant, not other medical care costs.

If the medicine/therapy to be trialled in the study is patented by a company, please state why the company is not financing the study.

The description may cover a maximum of 2 000 characters including blank spaces. This is approximately 1/2 A4 page in Arial, font size 11, single line spacing.

Publications

Please attach your publication list drawn up according to the headings and information below. The list shall cover a maximum of 5 page-numbered A4 pages in Arial, font size 11, single line spacing and 2.5 cm margins.

Sort the publications under each heading in reverse chronological order, so that the latest publication is at the top of the list. Please only include articles or equivalent that are published or accepted for publication at the time of applying. The author name order shall be identical to that of the published work. The application cannot be supplemented with publications after the deadline for the call.

1. Selection of publications: List the 10 publications of greatest importance to your application. Describe how you contributed to each publication, and its relevance to the research project described (maximum 4 lines per publication). Highlight your name in bold in the author list.

2. Relevant publications from the last 8 years: Sort the publications (published 2012–2020), with your name highlighted in bold in the author list, under each heading (publication type) in the following order:

- Peer-reviewed original articles
- Peer-reviewed conference contributions, the results of which are not included in other publications
- Peer-reviewed edited volumes
- Research review articles
- Peer-reviewed books and book chapters
- Other publications including popular science books/presentations

Administrating organisation

Please state the administrating organisation and project site.

Review panels

Please request the review panel or panels (in priority order) that you wish to carry out the scientific assessment of your application. The final allocation of applications is determined by the Swedish Research Council.

Review panels

Participants

Here you as applicant may invite participating administrators to your application. Please note that participating researchers may not be invited in this project outline.

CV

Under this tab, please upload your relevant CV information from your personal account in Prisma.

The following information (where available) must always be included in your CV:

- **Education:** First, second and third cycle higher education and specialist degrees.
- **Work:** Current employment (including employment form) and longer relevant employment held, postdoctoral visits (also included as employment if relevant), research exchanges relevant to the research described and any longer interruptions in the research that have impacted on your opportunity to gain merit as a researcher.
- **Merits and awards:** Docentship/associate professorship, supervisees (postdoctoral and doctoral students; state the number of persons in each category and list the names of the up to 10 most

relevant to you), up to 10 of your most relevant grants awarded in competition, up to 10 of your most relevant prizes and awards, and up to 20 other merits relevant to the application.
- **Intellectual property rights:** For example, patents and open access computer programs developed by you; state up to 10 of your most relevant.

How your application is assessed

Scientific quality is the fundamental criterion when the Swedish Research Council allocates grants to research. Your application is evaluated in competition with the other applications on the basis of the following evaluation criteria. The committee for Clinical Therapy Research lends support to clinical studies which are justified by the needs of the healthcare sector, and thereby offer important benefits to patients and society within a relatively short time frame. The applications for grants in clinical therapy research are assessed according to a two-step procedure. First, applicants are required to submit a project outline for evaluation. Applicants, who pass the project outline evaluation will subsequently be asked to submit a complete application.

Evaluation process

The project outlines for grants in clinical therapy research are assessed by review panels consisted of international researchers. The entire review panel then meets at a review panel meeting to discuss and prioritise the project outlines, and finally to make a proposal for a decision to the committee for Clinical Therapy Research. All project outlines will receive an individual final statement that reflects the review panel's discussion of the scientific quality of the application.

Review panels

Evaluation criteria and guiding questions

The evaluation of the scientific quality of your project outline is made based on five criteria (Scientific quality of the proposed research, Patient value – benefit of the research, Novelty and originality, Merits of the applicant, Feasibility). The purpose of using several components is to achieve a multi-faceted evaluation. Only project outlines that have been assessed to have high scientific quality and patient value will be asked to submit a complete application. Due to the nature of clinical therapy research, the Novelty and originality should be weighted lower than the other criteria.

No grading will however be done for the project outlines. The review panels make an overall scientific assessment based on the five assessment criteria and give the following scores

- *prioritized and asked to file a full application*
- *rejected.*

For the assessment of the full application a seven-grade scale is used for four of the assessment criteria: Scientific quality of the proposed research, Patient value – benefit of the research, Novelty and originality and Merit of the applicants. Feasibility is graded using a three-grade scale. The various criteria being used in the assessment will be weighed together to an overall grade (1—7), which reflects the overall assessment of the scientific quality of the application by the evaluation panel. Only applications that have been assessed to have high scientific quality and patient value will be consider for funding.

For each criterion, there are guiding questions to support the panel members' evaluation of your application. These can also function as guidance for you when you write your application.

Scientific quality of the proposed research (1–7)

Guiding questions:

- Is the project design sufficiently described according to the guidelines for the application?
- Is the main research question(s) motivated and specified?
- Is the primary outcome(s) and endpoint(s) well defined and the most appropriate?
- Is the proposed project design adequately designed? Would an alternative study design have increased efficiency?
- If any, which are the limitations of the project design?
- Are the variables and measurements/assessments, power calculations, sample size and patient selection convincingly described?
- Has the project a clear statistical analysis design that is linked to the research question?

- Is the project nationally coordinated? Please refer to the call text indicating that collaboration and/or patient recruitment from a minimum of four Swedish regions is a prerequisite to apply. Exemption may be possible for National Specialised Medical Care or diseases of relevance to few regions.
- Is there a need of more research in this area in accordance to existing systematic reviews, national and international guidelines and/or identified knowledge gaps? Have similar studies been conducted before?
- Will the results of the project fill an existing knowledge gap in the clinic?
- Have the applicants described if and how sex and gender are relevant to the research question?
- If sex and gender is described as relevant to the research question, have the applicants considered sex and gender in their description of the proposed work, including choice of study population, design, analyses, and implementation?
- If sex and gender is not considered in the description of the proposed work, including choice of study population, design, analyses, and implementation, have the applicants justified why this is the case?

Patient value – benefit of the research (1–7)

Guiding questions:

- May the results of the study be directly implementable into clinical practice within a relatively near future (2-10 years)?
- Have the target groups (patient groups, patient organizations, family members and others who may benefit from the research findings) been consulted in the planning of the study and the choice of endpoints?
- May the results of the study contribute to a significantly increased clinical benefits and/or less harms for the individual? Assessed clinical value can be influenced by prevalence, severity of the disease or social costs.
- May the results of the study contribute to a better use of healthcare resources?

Novelty and originality (1–7)

Guiding questions:

- Is there a need of more research in this area in accordance to existing systematic reviews, national and international guidelines and/or identified knowledge gaps?
- Have similar studies been conducted before?
- Will the results of the project fill an existing knowledge gap in the clinic?
- Does the project have the potential to deliver implementable results beneficial to patients and society?

Merits of the applicant (1–7)

Guiding questions:

- Do the team (applicant and the participating researchers) have sufficient research experience, expertise, and scientific network for performing the proposed project?
- Based on previous publications and other scientific achievements, does the team show a track record of high quality and ability to successfully disseminate research findings? (focus should be given to the most relevant and important publications and reports with emphasis on quality rather than quantity)
- Is there appropriateness of the team, if applicable, in terms of availability and complementarities of all the relevant expertise, and in how the different roles and responsibilities are distinguished?
- Has the applicant and/or any of the participating researchers been involved in critical evaluation of clinical studies or guideline establishment?

Feasibility (1–3)

Guiding questions:

- Is the recruitment of patients into the study feasible within the time frame of the project – have drop-outs and loss of enrollment in the recruitment due to holidays been taken into account?

- Does the project include the availability and accessibility of relevant personnel, including statistician, skills, equipment, facilities/ infrastructures and other necessary resources?
- Is the team composition and its environment suitable for carrying out the proposed research?
- Is there involvement of a clinical trials unit or any trial staff (if applicable)?
- Is it clear who is responsible for the data management?
- Is the time schedule optimal to carry out the proposed project within the timeframe of four years plus one year of availability period, totally five years?

Overall grade (1–7)

The above subsidiary criteria are weighed together into an overall grade, which reflects the review panel's joint evaluation of the application's scientific quality.

Report for previously awarded research grant

These guiding questions are only to be used for those project outlines where the project leader has earlier received a grant in Clinical Therapy Research. These questions should serve as guidance when assessing the preliminary scientific report for previously awarded research grant.

Guiding questions:

- Is there any relation between the ongoing project and the new proposal?
- If there is overlap, is a new approach presented in the current proposal? Is the new approach novel and justified?
- In what way will the envisaged project deliver reliable and implementable results that can offer large benefits to patients and society that the previously funded project has failed to do?
- Has the funding for the ongoing project been used according to the presented budget?
- Are there research resources not yet spent?
