

Assessment of grant application submitted to the Research Council of Norway

Grant application

Project number	295652
Project title	Continuation and strengthening of the Norwegian Clinical Research Infrastructure Network (NorCRIN) - "NorCRIN 2"
Project manager	Morken, Gunnar
Project owner	ST. OLAVS HOSPITAL HF
Application type	Research infrastructure
Programme/Activity	Nasj.sats. forskn.infrastrukt
Case officer	Kirsti Solberg Landsverk

Confirmation

By completing and submitting this form, I / we confirm the following (applies for the individual referee or the referee panel):

- I/We have no conflicts of interest that would prevent me/us from conducting this assessment. See Regulations on Impartiality and Confidence in the Research Council of Norway.	Yes
- I/We have read and understood both the criteria I/we have been asked to use for assessing the application and the description of the scale of marks. The scale of marks is to be applied as an absolute scale, i.e. marks are to be determined for each grant application independently and not relative to other applications that the panel/referee is assessing.	Yes
- I/We understand and accept the guidelines for assessing applications for the Research Council of Norway. See Guidelines for referees/panels who assess applications for the Research Council of Norway.	Yes
- I am/We are qualified to conduct this assessment.	Yes

Summary of marks

Criterion	Mark
Benefit to research of the infrastructure	7
Relevance and benefit to trade and industry	6
Relevance and benefit to society	A
Feasibility	7
Plan for establishment and operation of the research infrastructure	6
Quality of the application documents	A
Overall assessment of the referee/panel	7

Special points to consider	Answer
Internationalisation	Some
Ethical perspectives	Yes
Environmental impact	Neutral

Criteria

Benefit to research of the infrastructure

How would you rank the benefit of this infrastructure to research?

This criterion gives an indication of the impact of the establishment of the infrastructure on research activities within the relevant subject areas, and the significance of the infrastructure for the national research community. The benefit to research of the infrastructure will be assessed in relation to the following points:

- * Whether the research groups have documented expertise in the application areas as well as the level and scope of national research in the relevant area.
- * Whether the research infrastructure will open up new opportunities for Norwegian research groups compared to existing infrastructure.
- * The extent to which the research infrastructure contributes to scientific renewal, increases the scope of research activities, promotes the development of new knowledge, and drives research in areas of major national and/or international significance towards the research front.
- * How the research infrastructure will be applied in relation to existing infrastructure.
- * The potential to make Norwegian research groups attractive to the best researchers, nationally and internationally.
- * The capacity to carry out high-priority research that Norwegian research groups could not otherwise conduct on their own. (This applies to projects that require international cooperation on research infrastructure.)

The consortium has already demonstrated their capacity to work together in providing coordination, standard operating procedures and the development of clinical trial infrastructure that can lead to high-quality science. A number of clear examples of high-quality case-studies arising from work to date are identified.

This application is for funding that will leverage a very much larger sum from the institutions comprising the application, and also offers a clear path to independent funding and therefore provide a large scientific benefit for the infrastructure provided by this funding.

This start-up funding is intended to continue the work already in place, and establish a number of clearly defined improvements to the infrastructure, The Panel judged these as challenging areas that are essential to be addressed if Norway research (which has the major advantage of homogenous hospital systems and world-leading registries) is to maintain international competitiveness and remain attractive to industry.

This application sets out a strong case for its potential for scientific renewal and a wider scope of research activity. Examples cited include the potential for low-cost pragmatic trials using the registries, more rigorous design and conduct of trials (to meet increasingly rigorous expectations), and development of new designs to address challenges of personalised and diagnostic medicine.

There is a clear plan for transforming the current NORCRIN structure, an aspiration to collaborate with other networks (which will be facilitated by the hosting institutions).

This project sets out a clear and detailed vision of how it will make Norway research groups attractive and competitive.

There were no significant weaknesses in the way that this infrastructure would provide benefit to science.

Selected mark : 7 - Exceptional

Relevance and benefit to trade and industry

How significant will the expertise/knowledge developed in the project be for future value creation in Norwegian trade and industry?

This criterion gives an indication of the anticipated potential of the expertise/knowledge developed in connection with the project to generate value added in Norwegian trade and industry. The relevance and benefit to trade and industry will be assessed in relation to the following points:

- * The need for this expertise among the participants from industry
- * The need for this expertise within Norwegian industry at large
- * The potential of the increased expertise to trigger new growth in Norwegian industry

International clinical trials standards and practice are rapidly changing - and a national infrastructure at scale to coordinate training and best practice is essential. Addressing these areas, as planned by the team is essential if clinical research in Norway is to remain attractive to industry, and critical to supporting independent researchers.

Any improvement in trial management, including drug development, clinical trials and so is likely to positively impact healthcare and help reduce healthcare spending. Hence, there is at least an indirect positive impact to be expected from the successful implementation of this infrastructure

Healthcare industry (SME and large companies) will be interested in supporting high-quality data generation/management and data use for trials. Through their engagement in Advisory Boards (Fig 9.1.) and in WP11, their role should be better defined.

Selected mark : 6 - Excellent

The project will generate expertise/knowledge that represents a basis for significant value creation in Norwegian trade and industry. The project will provide a significant contribution with regard to several of the assessment points, and will contribute positively to the others.

Relevance and benefit to society

To what degree will the project be of relevance and benefit to society?

This criterion gives an indication of how the project will contribute to knowledge/competence of significance to meeting societal challenges.

In this context, the phrase “of significance” refers to how the knowledge/competence may be useful in meeting challenges in the public sector, industry or civil society viewed in a regional, national or global context.

The inclusion of two elements, in particular, make this of relevance to wider society. Firstly the creation of a robust public and patient initiative associated with the conduct of clinical trials has the potential to engage wider society in all stages of the process from trial design, conduct, interpretation and dissemination
By fostering a high-quality environment for researchers, Norway becomes (even more) attractive to anyone who likes to do applied science. Supporting the generation of high-quality data will positively impact research in data analysis and management, including computer sciences etc.

Selected mark : A - Very good

The project will lead to knowledge/competence that is of great importance for dealing with societal challenges.

Feasibility

How feasible is the project?

This criterion gives an indication of the extent to which the infrastructure project is feasible with regards to the technical solutions, available expertise, and personnel as well as financial resources involved.

Feasibility with regard to technical solutions will be assessed in relation to the following points:

- * Whether the proposed solution has sufficient technological maturity to result in an infrastructure that can be applied in research.
- * Whether the proposed solution is among the best available state-of-the-art solutions. Alternatively: Whether it has been documented that no available solutions exists in the market, which gives good grounds for independent development.
- * Whether the methodology/technology on which potential independent development is based has been demonstrated as functional in a relevant environment (Technology Readiness Level 6 as defined in the European Commission).
- * Technological risk and proposed measures for dealing with any high-risk incidents.

Feasibility with regard to the available expertise will be assessed in relation to the following points:

- * Whether the project manager and project group have the expertise needed to establish and operate the research infrastructure.
- * Whether the applicant institution has the expertise needed to host the research infrastructure.
- * The contribution of any partners to the quality of the project.
- * Risk associated with the available expertise and proposed measures for dealing with any high-risk incidents.

Feasibility with regard to personnel resources will be assessed in relation to the following points:

- * The project's need for personnel resources, as listed in terms of work time distributed by work packages/sub-projects or milestones.
- * Whether the applicant institution has resources needed to host the research infrastructure.
- * The contribution of any partners to the personnel resources in the project.
- * Risk associated with access to skilled personnel and proposed measures for dealing with any high-risk incidents.

Feasibility with regard to financial resources will be assessed in relation to the following points:

- * Whether the level of overall investment costs is correct and necessary.
- * The funding plan for establishment as well as operation of the infrastructure.
- * Financial risks and proposed measures for dealing with any high-risk incidents.

All of the processes proposed here are feasible for immediate application. The design of this initiative builds on what is already in place. It puts in place further networking and identifies specific priorities on which further focus and collaborative effort would lead to major change. The work to date with the network structure shows that it is feasible (although the detail provided about the success of NORCRIN-1) is limited in this application. The only area where some risk exists is in the aspiration to use registries for clinical trials. Although the technology here is mature, the practicalities involved in using registries and dealing with GDPR (for example) can be complex and further work needs to be done to address these.

The key to this application is the continuation of a governance structure that is already in place and includes senior strategic leadership from each of the institutions involved. The proposed chair is a senior clinician with substantial expertise in research management, there is a similar spread of individuals with very relevant expertise among the applicants. This includes major trial experience and research nursing experience.

Selected mark : 7 - Exceptional

Plan for establishment and operation of the research infrastructure

How well-suited are the plan for establishment and operation of the research infrastructure in relation to the project?

This criterion gives an indication of whether the plan for project implementation is satisfactory, and whether the planned use of resources in the project is well-suited for the tasks in the project, based on assessment of the following elements:

- * Plans for the establishment of the infrastructure, including breakdown into work packages/sub-projects, milestones or deliverables.
- * Plans for the operation of the infrastructure, including how the infrastructure will be made accessible to relevant users (also external users) and indicators for measuring the infrastructure's quality.
- * The ability of the consortium to ensure optimal utilisation of the infrastructure.
- * Plans for data management, i.e. plans for storing the data generated, and publishing or making it accessible in other ways.

The operational structure proposed with an executive committee and secretariat, and a representative governance council provide a robust and well thought through way too ensure that NORCRIN-2 can follow the strategic approach set out in this document, whilst responding to new challenges that may emerge over the next ten years.

There is a need to start towards the development of more robust metrics for network activity.

WP8: the "training" activities should entail webinars, local training seminars and activities during consortium meetings (not defined). WP should aim for a higher budget to support training.

WP13 is very important; engagement in social media and approaches like <https://ois.lbg.ac.at/en/methods-projects/ois-activities> missing; funding should be increased because patient / public engagement is very important and rarely done.

Generally, the outcome/results of NorCRIN-2 need to be on display to the various stakeholders. This could start to be addressed

Selected mark : 6 - Excellent

Quality of the application documents

How would you rank the quality of the application documents?

This criterion gives an indication of the extent to which the application documents are satisfactory as a basis for assessing whether a project should be granted funding. The information and plans that have been requested must be clearly described.

This is a professionally composed application that reads well. Personally, the graphs and tables are sometimes hard to read/follow. The details for funding requests for individuals could have usefully been included.

Selected mark : A - Very good
All the requested information and plans have been clearly described and are easy to follow.

Overall assessment of the referee/panel

How does the project rank in terms of the referee's/panel's overall assessment?

This criterion indicates the overall view of the referee/panel, based on the specific criteria which they have been asked to assess.

This application sets out a strong case for the potential for scientific renewal and a wider scope of research activity offered by NORCRIN2. Examples the team cite include the potential for low-cost pragmatic trials using the registries, more rigorous design and conduct of trials (to meet increasingly rigorous expectations), and development of new designs to address challenges of personalised and diagnostic medicine. There is a clear plan for transforming the current NORCRIN structure, an aspiration to collaborate with other networks (which will be facilitated by the hosting institutions). This project sets out a clear and detailed vision of how it will make Norway research groups attractive and competitive, They build on the success of NORCRIN-1. Clinical trials are a challenging area, and this application makes a strong case that Norway infrastructure in this area needs to be coordinated, networked and standardised. The work to date (for example with standard operating procedures) is only a small part of what is a rapidly changing field. The funding requested is only a small (but important part) of a much wider initiative that would have strong relevance to wider society and industry. The proposal is well developed, feasible and well presented.

Selected mark : 7 - Exceptional

Special points to consider

Special points to consider	Answer
Internationalisation	Some
Ethical perspectives	Yes
Environmental impact	Neutral

Comments to special points to consider