Clinical therapy research in the specialist health services

Abbr.: KLINBEFORSK

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Programme plan 2018

(*abridged*)

Background

Clinical trials give patients an opportunity to receive new, experimental therapies and provide the health service with new knowledge and information to support development of preventive measures, diagnostics, treatment and rehabilitation. In Norway, a limited number of clinical trials is offered to patients, and the size of such studies is often small. In order to meet the needs for large, national clinical trials of high quality with predictable funding, the Norwegian Ministry of Health and Care Services in 2016 initiated a joint effort to support clinical multicentre studies in Norwegian hospitals. The initiative has been organised as a research programme - *Clinical Therapy Research in the Specialist Health Services (KLINBEFORSK)* – and is to be aligned with needs identified by patients, the service, policy makers and researchers.

Increasing the number of larger clinical trials is in line with the objectives of the *Long-term plan for research and higher education 2015-2024*[1], aimed at strengthening Norway's competitiveness and innovative assets in order to solve major societal challenges and develop academic environments of international quality. In the *HealthCare21*-strategy[2], increasing the number of clinical trials is also included as a specific goal.

The regional health authorities own KLINBEFORSK jointly to create a link between clinical research, treatment of patients and identified needs of the health services. The programme administration is located to Helse Sør-Øst RHF to provide support for application processes and follow-up of projects financed by the programme.

KLINBEFORSK is set up to contribute to cover knowledge gaps in areas where needs have been documented. To this end, needs identified research, as described in *Legemiddelmeldingen*[3], should be used. This includes defining processes for knowledge generation, refinement of hypotheses, involvement of patients and other users, as well as evaluation and prioritization of research targets.

Clinical Therapy Research - definition

Clinical therapy research encompasses interventions with the inclusion of patients, aimed at improvement of existing treatment practices, use of pharmaceuticals and medical technology and / or the development and evaluation of new ones. Examples of such studies also include comparative efficacy studies and evaluation of diagnostic methods and/or established drugs as well as research aimed at streamlining treatment processes and procedures.

Comprehensive research funding

KLINBEFORSK receives funding over chap. 732 post 78 from the *Norwegian National Budget*. *South-Eastern Norway Regional Health Authority* handles the budget and acts as an administrator on behalf of the other regional health authorities.

KLINBEFORSK will complement national and international funding sources and thus contribute to a more cohesive funding situation for Norwegian health research. The programme is also featured in the annual documents given from the *Norwegian Ministry of Health and Care Services* to the regional health authorities[5].

Programme objectives

The main objectives of establishing this programme are to give more patients the opportunity to receive experimental therapies as well as to contribute to increased coordination of expertise, resources and infrastructure and strengthen the provision of health services that are efficient, safe and of good quality.

Thematic limitations

The programme is thematically open to all clinical disciplines, however, the overarching goal is to meet needs and fill knowledge gaps that are of the greatest importance to patients. Medical needs are identified by systematic reviews, e.g. conducted by the *National System for the Introduction of New Health Technologies (methods) within the Specialist Health Service*.

Large disease groups representing a significant societal challenge are particularly relevant to the programme. However, this does not exclude clinical investigations involving smaller and more vulnerable populations if the need for new knowledge generation is substantial.

Purely epidemiologic and genetic studies, observational clinical trials, health services research, translational research, basic medical research and similar investigations are not considered within scope of the programme.

The projects may utilize national health registries in comparative efficacy studies by including patients from across the country in randomized trials. Studies based on patient records must also fulfil criteria as interventions and meet the general requirements concerning participation of research institutions from all health regions.

Needs identification

The programme will contribute towards knowledge gain in areas where there are documented gaps identified by e.g. systematic reviews. The instrument "needs identified research", as described in *Legemiddelmeldingen*[3], will be developed. To this end, systems will be established to ensure that researchers, patients, health care personnel and policy makers in the specialist health services will be able to provide input and feedback to the formulation of relevant research questions.

Research networks

National research networks should facilitate close collaboration between researchers within a defined area to strengthen quality of research and overall research production. *The Ministry of Health and Care Services* has given the regional health authorities the task of establishing national research networks in areas where there is a defined need, including personalized medicine.

Support for setting up a national research network may be included as part of a project application to the Programme for Clinical Therapy Research, however, funding for networks is not available as a separate application category.

User involvement

Users should be able to influence the design and implementation of the research projects. Relevant users/user groups should be identified, and the scope, content and significance of user involvement should be described, including how a user perspective is maintained throughout the project.

Research collaboration

International collaboration

International research collaboration is central to improving the Norwegian coordination with scientific development in the rest of world and contributes to improved quality of research in Norway. Closer coordination of clinical research in the Nordic countries provides a much larger patient base for clinical trials. This may be of particular importance for development of personalized medicine and definition of patient groups on the basis of genetic markers. Projects funded by KLINBEFORSK may be part of a Nordic or international collaboration, however, it is assumed that the Norwegian branch of the project has a key role in all aspects of the project including publication and dissemination of results.

Collaboration with industry

Health research environments in Norway have only limited collaborations with industry. The *HelseOmsorg21*-strategy states that the health care sector needs to improve interactions with industry in order to meet their targets. A strong and innovative industry sector that assimilates the ideas and innovations from research is also a prerequisite for building good health care services for the future.

The programme for clinical therapy research is open to industry collaborations, provided that the study meets the needs of the patient and the service and originates from a hospital.

Evaluation of applications

Assessment of project applications to KLINBEFORSK is based on quality and expected impact/benefit to patients using evaluation criteria developed by the four regional health authorities.

Reporting

All funded projects must register the study in kliniskestudier/helsenorge.no. Projects registered in CRIStin should be using the *Health Research Classification System* (HRCS). Programme results and impact may be subject for evaluation by *HelseOmsorg21 Monitor*.

Project guidelines

- Hospitals or private institutions given access to funding from the regional health authorities may apply to the programme
- Projects should include active participation from all health regions. This is also contributing to provide equal access for patients from all regions.
- The project period is limited upwards to five years. Total budget for this period should be in the range of 5 to 20 million NOK.
- National research infrastructure, NorCRIN, may be used.
- It is assume that hospitals/institutions participating cover expenses for regular treatment of patients included in the studies. Additional infrastructure costs for project implementation, such as monitoring, user involvement etc may be added to the budget.
- Annual project reports should include status for the project and an overview of costs incurred over the project period.

References

1. Meld. St. 7 (2014-2015), Langtidsplan for forskning og høyere utdanning 2015-2024
2. HelseOmsorg21, Et kunnskapssystem for bedre folkehelse, Nasjonal forskning- og innovasjonsstrategi. Rapport 2014
3. Meld. St. 28 (2014-2015), Legemiddelmeldingen, Riktig bruk – bedre helse
4. Program for God og treffsikker diagnostikk, behandling og rehabilitering (BEHANDLING), programplan 2016-2015, Norges Forskningsråd
5. Helse- og omsorgsdepartementets oppdragsdokument 2016 til de regionale helseforetakene.
6. Prop. 1 S (2015-2016), for budsjettåret 2016, Statsbudsjettet.
7. Regjeringa sin handlingsplan for oppfølging av HelseOmsorg21-strategien. Forskning og innovasjon i helse og omsorg (2015-2018).