Nordic Collaboration on Clinical Research Infrastructures (NordicCRIS)

Introduction

The "Nordic Collaboration on Clinical Research Infrastructures" was established 25th April 2025 in a Nordic meeting taking place in Oslo, following an initiative from the NorCRIN work package for International Collaboration. The network represents an independent collaboration between research support organizations in the Nordic countries (Island, Finland, Sweden, Norway and Denmark), with an interest in both academic and industry-initiated clinical studies.

Aim and Scope

Primary Aims: To strengthen Nordic collaboration between clinical research infrastructures and contribute to harmonization and optimization of operational and administrative research support in clinical studies. The objective of reducing workload for clinicians and health care staff will facilitate more clinical research, foster scientific excellence, and ensure patient safety in clinical trial.

Scope:

- Inclusion of both public, academic and commercial stakeholders
- Share experiences and information, address common challenges and strategic goals
- Collaboration on operational research support development within the Nordic countries
- Competence enhancement and sharing of best practices of research support staff and researchers
- Represent a unified Nordic voice in relevant European and global perspectives, ensuring Nordic conversations and development
- Facilitate participation from Nordic sites in international multicentre trials
- Promote collaboration with existing Nordic networks and prevent duplication of efforts
- Work towards easier access for Nordic patients to participate in relevant research protocols across the Nordic countries
- The network should define clear goals, tasks, and priorities, while remaining flexible and responsive to change

Organization

This collaboration operates on an informal basis, without strict membership requirements. No formal leadership nor specific partners are appointed. A coordinating group with two members from each country is established, primarily serving as a point of contact for the different stakeholders. The coordinators are responsible for convening meetings, facilitate the network activities, and disseminate relevant information among members.

The intended audience for regular meetings includes members of research infrastructure networks, administrative research support staff, as well as clinical researchers and study personnel. Representatives from commercial parties, regulatory authorities, subject-specific

organizations (cancer, personalized medicine/precision medicine, medical devices etc.), international organizations (ECRIN, CRIGH, WHO etc.) and others may be invited to meetings on a theme-by-theme basis.

National coordinators (alphabetically):

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A temporarily website will be organized on www.norcrin.no to serve as

- Information platform for all stakeholders
- Point-of contact information for the coordinating group
- Agendas, presentations and summaries from meetings
- Newsletters and plans for activities and topics to discuss
- Overview Nordic research support network (to be updated when needed)

Content will be updated by NorCRIN as long as norcrin.no is used as a common website

Meetings and agenda

- 2 Teams-meetings per year. Working groups for collaborative activities may meet in between, reporting at the meetings 2 times per year.
- Physical meeting every second or third term, preferably organized in connection with other conferences (e.g. our national equivalents).
- Physical meetings should preferably be full-day events

The coordinating committee is responsibility for the agenda and meeting invitations.

Meeting lead may rotate among countries according to the rotation schedule:

- NorCRIN: 25th April 2025 (Gardermoen, Oslo)
- Norway: September 2025 (digital)
- Sweden: Spring 2026
- Denmark: Workshop (physical) in Denmark by OPEN (spring 2026)?
- Denmark: Autumn 2026
- Finland: Spring 2027
- Iceland: Autumn 2027

A list of suggested topics for future meetings is provided below and will be discussed among participants and posted at the website. Any new suggestions should be mailed to the members of the coordinating group, who are responsible for suggesting topics for upcoming meetings. The agenda will be circulated 2 weeks in advance of planned meetings.

Meeting duration Teams: 60 - 120 minutes

Meeting duration physical meeting: full day events (taking travel distances into consideration)

Currently there is no funding for this network, and any cost (e.g. meeting arrangements, travelling, website etc.) will be covered by national entities on a case-by-case basis pro bono. It will be necessary to pursue external funding to ensure optimal functioning of the network, i.e. for undertaking physical meetings, workshops, webpage and project development.

Suggested of topics for future discussions

A. Building an active Nordic network to increase competence on

- EU Clinical Trials Regulations and GDPR (general data protection data regulation)
- Advice towards MD (medical devices), EU-MDR (medical device regulation) and IVDR (in vitro diagnostic device regulation)
- Safety reporting (pharmacovigilance)
- Data sharing (FAIR) (might involve the libraries)
- Application of AI in clinical research

B. Sharing experiences

- Regarding financing and pricing of research support services
- To develop our knowledge so that we can offer research support in primary healthcare (lessons learned when involving GP + municipalities)
- Recruitment of patients in clinical studies across the Nordic borders
- Application/accreditation of Nordic institutions as state-of-the-art centres (such as Comprehensive Cancer Centre)
- International Platform studies
- Pragmatic clinical trials
- Risk based trial design and monitoring

C. New opportunities

- Collaborate on competence enhancement for clinical trials staff and new target groups (i.e. GPs in primary health care, PhD students, managers etc.)
- Promoting the Nordics as an attractive region for collaboration with the Pharma and MedTech industry, including Nordic point of contact
- Facilitate operationalization of WHO resolution/WHO guidelines in the Nordic region
- Strengthen the Nordic relationship with European Clinical Research Infrastructure Network (ECRIN) and Clinical Research Initiative for Global Health (CRIGH)
- Research funding (e.g. Nordic authorities and EU)

D. Topics for workshops on operational research support

Idea for workshop concept: Approximately 2 days, depending on topic and needs. Hosting the workshop can be on rotation. Each participating organization contributes with a relevant talk about the subject (gap/problem or sharing expert knowledge/best practice) followed by group discussions. The host may organize a site visit/this fieldtrip at their discretion.

- Budget and economy: How to plan a budget covering all the needs in clinical trials, and how to ensure compliance and a healthy economy throughout the trial. How to negotiate a robust budget when cooperating with industry or academic partners?
- Inclusion in clinical studies across borders: Explore strategies for how patient inclusion in clinical trials across borders be achieved. How can informed consent processes and utilization of e-consent platforms be aligned?
- Best practice for Writing a protocol: What are the best practices in writing a good protocol, which templates can be recommended, and what aspects are important concerning approval by the Nordic authorities.
- Best practice for Data management: Data collection and quality, risk assessment. Data governance and data management plans. Assessment of electronic systems/data capture tools and ensuring fulfilment of requirements by legislations/regulations and the authorities. Data governance regarding updates of the EU-regulative (i.e. ICH GCP R3 guideline).
- How to plan a clinical trial: Discussions based on knowledge and experience of what is important to know before starting a clinical trial, and where to have a heightened focus in the planning process. Issues relating to reporting of the project in accordance with protocol and agreements:
- Management, organization and development of CTU services: Comparison between CTU units and services. Best practices in how to establish, organize and run a CTU. Which kind of services can and should be provided, and how to communicate these to the researchers and trial staff.
- Sponsor project manager: There is a need for trained Clinical Research Associates (CRAs) in multinational trials with Nordic sponsors. Workshop on sharing of best practices and opportunities for competence enhancement.