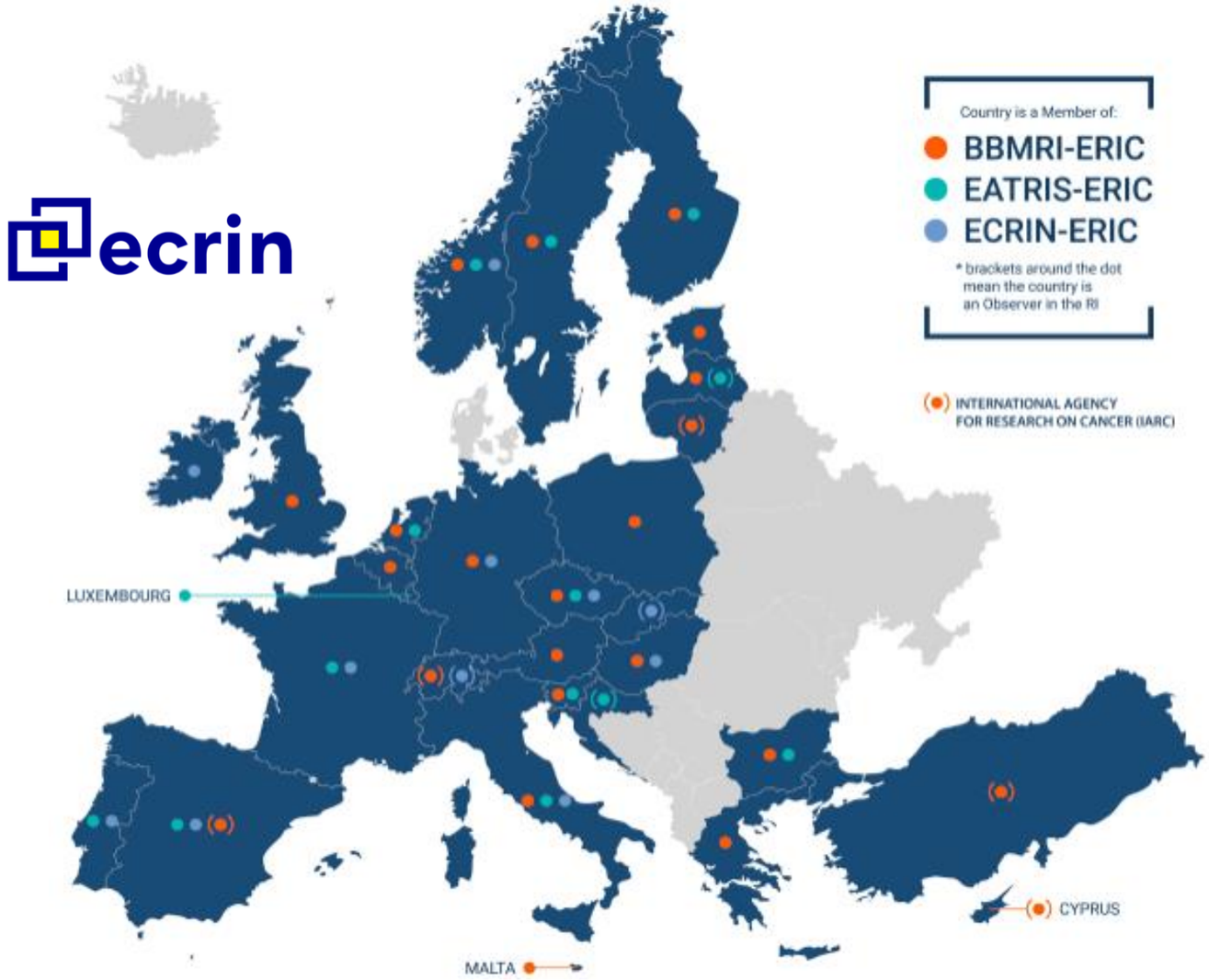
Nordic Cooperation on Clinical Research Infrastructure Network

Exploratory and Establishment Meeting

Oslo, 25th April 2025

NorCRIN

European and global Clinical Research Infrastructure Networks



ERIC: European Research Infrastructure Consortium

ECRIN: European Clinical Research Infrastructure Network

BBMRI: Biobank Medicine Research Infrastructure

EATRIS: Translational Medicine Infrastructure

Global:

CRIGH: Clinical Research Initiative for Global Health

WHO: World Health Organization - Guidelines Clinical Trials

CRIGH

World Health Organization

Participants list

Sweden	Denmark	Finland	Island	Norway
Anna Ramnemark Emma Larsson Ann Tronde Maria Sörby Verena Sengpiel Gunilla Andrew-Nielsen Åsa Michelgård Palmquist Ana Caneiro	Martin Højgaard Anna Skat Nielsen Janni Brødbæk Marianne Pihlgaard Helle Toldbod Louise Hansen Charlotte Schmidt Skov	Mia Bengtsröm	Halla Sigrun Arnardottir Thorvardur Löve	Øyvind Melien Ole Alexander Opdalshei Signe Fretland Jon B. Borgaard Martha Colban Svein Skeie

NorCRIN Coordinating Unit (organizer)
Nina Louise Jebsen Sigrun Margrethe Hjelle Marianne Saugestad

Special Guests
Bjørn Gunnar Iversen Bent Håkon Lauritzen Åslaug Helland

NorCRIN

Agenda

10.00-10.30	**Opening and introduction** • Welcome remarks from the NorCRIN Secretariat • Short around the table introduction of meeting participants • Introduction to the objectives of the meeting and overview of the agenda • Importance of viewing the Nordic region for clinical trial cooperation
10.30-11.20	**National clinical trials support network: current status and visions** • Norway: Nina Louise Jebsen • Sweden: Anna Ramnemark • Denmark: Marianne Pilgaard • Finland: Mia Bengtström • Island: Halla Sigrun Arnardottir
11.20-11.40	**Coffee break and mingling**
11.40-13.00	**Established networks for Nordic collaboration, a brief overview of objectives, succ bottlenecks** • Nordic Trial Alliance - Ole Alexander Oppdalshei • Nordic Molecular Tumor Board (NMTB) - Martin Højgaard • Nordic Proof - Bent Håkon Lauritzen • NordicPedMed - Sigrun Hjelle • Nordic Research Preparedness Initiative (NRPI) - Bjørn Gunnar Iversen • NUHA agreement (Nordic University Hospital Alliance) - Åslaug Helland • Nordic Monitoring Network (NORM) - Åsa Michelgård Palmquist
13.00-13.45	**LUNCH**

13.45-14.00	**Nordic contact interface with international/global networks (WHO, CRIGH, ECRIN)** • The potential global role of this Nordic cooperation? • Implementing WHO resolution guidelines for multi-centre trials in the Nordic region
14.00-14.30	**Open discussion** Decision on: • Formation of a Nordic clinical trials support infrastructure network, based on experien established structures • Identifying key stakeholders and ensuring the right people are involved: network repre Others?
14.30-14.50	**Coffee break and mingling**
14.50-15.20	**Next Steps** Decision on: • Establishment of a coordinating group • Meeting format and frequency • Name for this Nordic cooperation on Clinical Trials Infrastructure Network • Scope of activities (framework) • Relation to regulatory authorities • Topics for next meeting (see next page) • Date for next meeting
15.20-15.30	**Closing Remarks** • Final reflections on the meeting • Thank you to participants

NorCRIN

Nordic Clinical Research Infrastructure Network?

Bring together Nordic colleagues and key representatives

Discuss aims, challenges and opportunities

Share experiences within and outside the network

NorCRIN

National clinical research support networks: current status and visions

Norway

Nina L. Jebsen

NorCRIN	NorCRIN - **Norwegian Clinical Research Infrastructure Network** is the Norwegian node of ECRIN with the primary objective to strengthen, harmonize and simplify collaboration in all categories of clinical research in Norway. NorCRIN provides support, education and standard operative procedures (SOPs) covering all steps of planning and conduct of a clinical trial (all SOPs are freely available in English at the homepage).
NorTrials	NorTrials is a partnership between the regional health authorities in Norway and the organizations for the pharmaceutical (LMI) and medical equipment (Melanor) industries, established on assignment from the Ministry of Health and Care Services. The purpose is to increase the volume and quality of clinical trials on drugs and medical equipment and thus give Norwegian patients increased access to new treatment methods through participation in clinical trials.
PRAKSISNETT	The Norwegian Primary Care Research Network (in Norwegian: **PraksisNett**) is a research infrastructure that provides a foundation for enhancing the quality of primary care research in Norway. The infrastructure facilitates recruitment of primary care patients to clinical studies and increases the power and predictability of these studies.
Biobank Norway	Biobank Norway is a national biobank infrastructure for global research collaboration. Biobank Norway is one of the world's largest biobank resources, encompassing both consent-based population biobanks and disease-specific clinical biobanks. It provides access to exceptional longitudinal health data, making it a unique and valuable asset for international research and innovation in life sciences, disease prevention, and treatment.
Nasjonalt kompetansenettverk for legemidler til barn	NorPedMed is a national clinical research network for pediatric drug trials, where research units and pediatric departments at university hospitals play a central role

New webpages March 2025

www.norcrin.no

- Established 2012 (academic research)
- 6 university hospitals – one national network for research infrastructure
- Funding from the Norwegian Research Council (2015-2025)
- Strengthen research collaboration nationally and internationally (ECRIN)
- Improve quality and increase quantity of clinical research
- Clinical Trial Units supporting both industry-initiated and academic trials

NorCRIN – counselling and conveyances

Protocol writing
Financing
Applications (NoMA/REC)
Contracts/legal issues
Clinical Trial Units
Data handling tools
Monitoring
SUSAR-reporting
Research networks
Int. Clinical Trials Day

Research support

Protocol template
Flowchart SOPs
Roles & responsibilities
Implementation & conduct
- medical drugs
- medical devices
- other interventions

Data handling
Statistics

Procedures

Teaching courses
- GCP
- statistics
- study nursing
- medical devices

Seminars
- monitoring
- data handling
- user involvement
- safety reporting

Competence

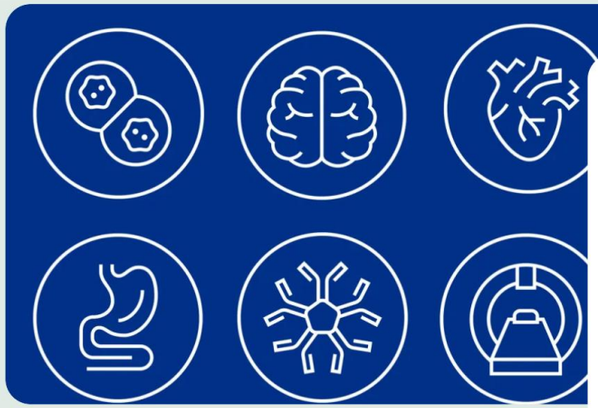
NorTrials

SEARCH MENU

NorTrials

NorTrials is a national partnership to increase the number of clinical trials in Norway. NorTrials contributes to a more efficient infrastructure and increased collaboration on industry-funded clinical trials in Norway.

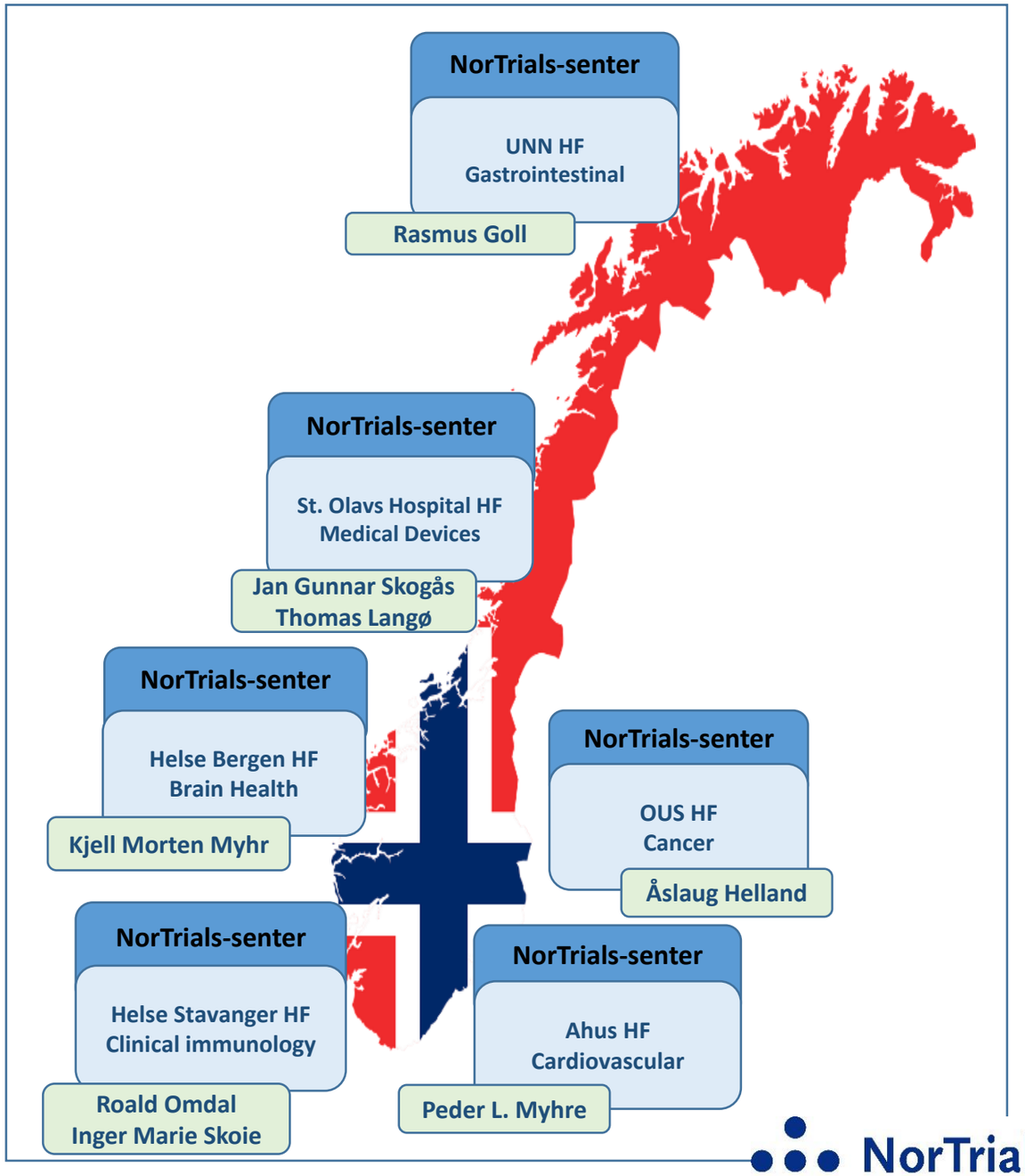
Norsk →



NorTrials Centres

NorTrials has established six dedicated clinical research centres within defined therapeutic areas.

NorTrials Centres →



NorTrials

NorTrials feasibility portal

NorTrials feasibilityportal

Obligatoriske felter er merket med stjerne *

NorTrials Feasibility Portal offers access to contacts at all Norwegian hospitals, for companies that want to carry out clinical trials in Norway.

This form will be recieved by NorTrials coordinating unit and forwarded to contact persons at the hospitals. The information will not be shared with any other parties.

General questions can be directed to contactnortrials@ous-hf.no.

Read more about NorTrials.

NorTrials

Name of contact person *

Email adress (contact person) *

Company name *

Clinical Trial information

Clinical Trial title

Category

- [ ] Investigational Medicinal Product
- [ ] Medical Device
- [ ] Pediatrics
- [ ] Rare Diseases

Therapy area *

- ○ Blood
- ○ Cancer
- ○ Cardiovascular
- ○ Congenital Disorders
- ○ Ear
- ○ Eye
- ○ Infection
- ○ Inflammatory and Immune system
- ○ Injuries and Accidents
- ○ Mental Health
- ○ Metabolic and Endocrine
- ○ Musculoskeletal
- ○ Neurological
- ○ Oral and Gastrointestinal

NorTrials

NorPedMed – a national network for paediatric research units

Nasjonalt kompetansenettverk for legemidler til barn

KOBLE Søk Meny

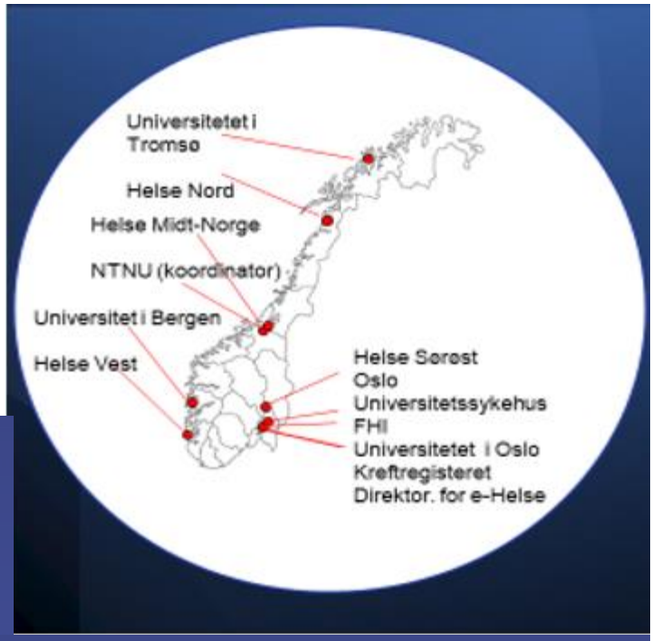
Legemidler til barn › Medicines for Children Research Network, Norway - NorPedMed

Medicines for Children Research Network, Norway – NorPedMed

Medicines for Children Research Network, Norway (NorPedMed) is a nationwide clinical research network. NorPedMed is a joint initiative from the Norwegian Health Directory and Medicines for Children Network, Norway.

PRAKSISNETT

Norwegian Primary Care Research Network



Biobank Norway

National clinical research support networks: current status and visions

Sweden

Anna Ramnemark

Nordic meeting Oslo April 25th

Anna Ramnemark

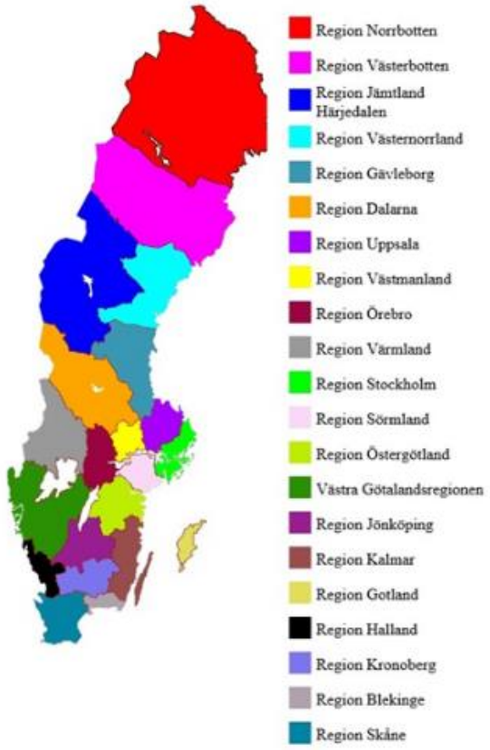
Clinical Studies Sweden

Advancing Clinical Research through National Infrastructure and Support

Current Status and Vision

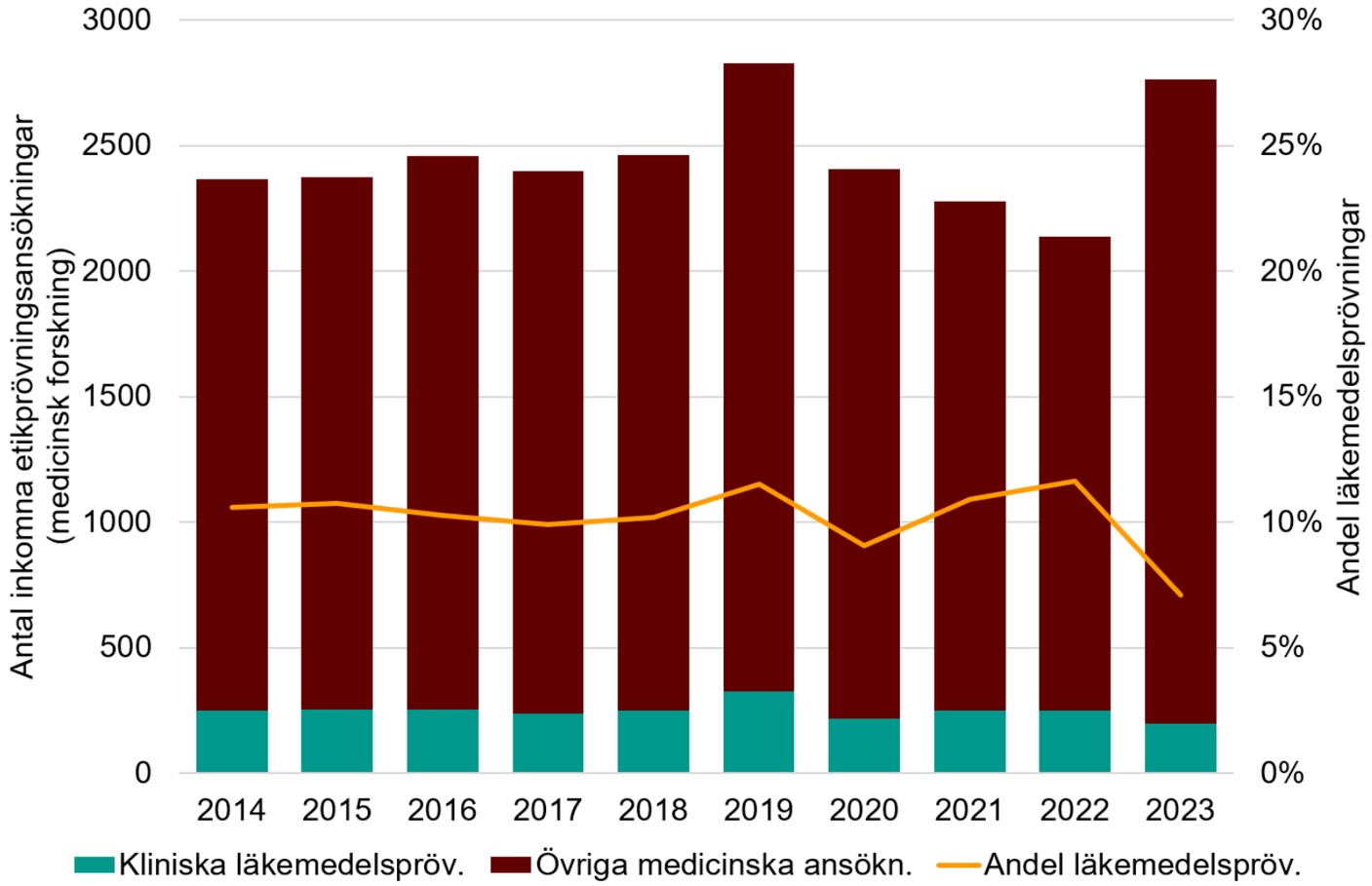
Clinical Studies Sweden

The Swedish Health Care System



Clinical Studies Sweden

Ethics review applications medical research



Etikprövningsansökningar för kliniska studier - Vetenskapsrådet

Clinical Studies Sweden

Clinical Studies Sweden

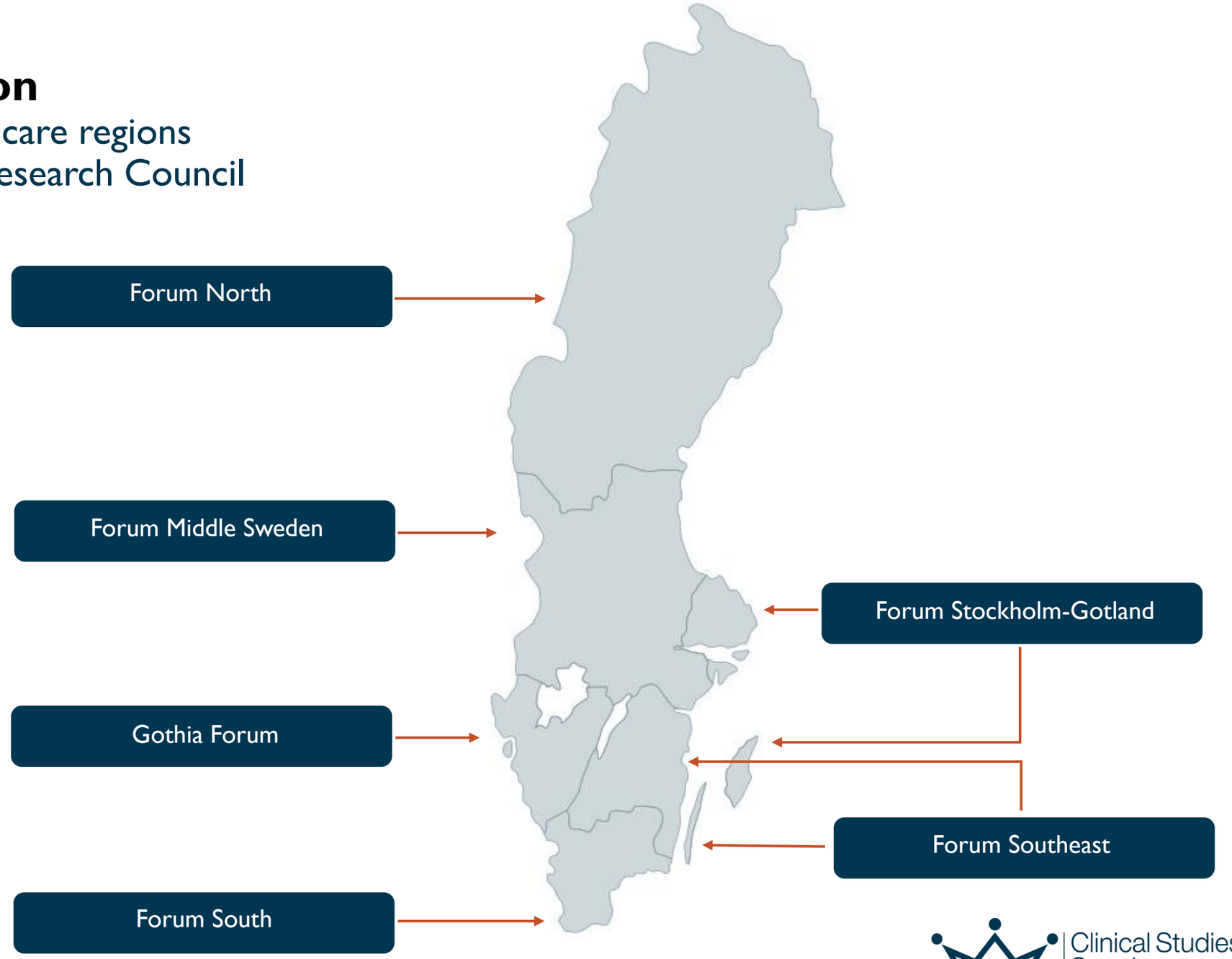
We develop and offer support and services to researchers, research staff and life science companies for the conduct of high-quality clinical studies throughout Sweden.

Vetenskapsrådet

Clinical Studies Sweden

National collaboration

Between Sweden's six healthcare regions
Supported by the Swedish Research Council



Clinical Studies Sweden

Our vision

Clinical studies are an integrated part of healthcare.

This creates the conditions for generating more knowledge, enabling more patients to participate in studies and, in the long run, providing better healthcare and general health.

Clinical Studies Sweden

Our strategic goals

- Be a natural **partner for both national and international collaboration** on clinical trials in Sweden.
- Provide a **research infrastructure within healthcare** that enhances the ability of researchers and life-science companies to conduct high-quality clinical studies.
- Serve as a **national entry point** for support and contact to facilitate clinical studies within Swedish healthcare.
- Strive to ensure **equal opportunities for patients** to participate in clinical trials.
- Establish a **strong knowledge organization**, trusted to meet both current and future needs for conducting clinical trials in healthcare.

Clinical Studies Sweden

Clinical Studies Sweden

Development and support of clinical studies in healthcare

Research support

Templates and supporting documents

Training

Kliniskastudier.se/english

Clinical Trial Units

Feasibility Sweden

Clinical Studies Sweden

Clinical Trial Units

- Located in hospitals with access to healthcare infrastructure for clinical research
- Conduct clinical studies on behalf and in collaboration with healthcare, academia and life science companies
- Experienced in several different therapeutic areas and different routes of drug administration (i.e oral, nasal, inhalation, dermal, i.v)
- Experienced in medical device, ATMP, all phases of drug development, clinical research and cohort studies
- Regularly inspected by the Swedish Medical Products Agency and are approved to conduct studies in all clinical development phases, First-in-Human to Phase IV

Clinical Studies Sweden

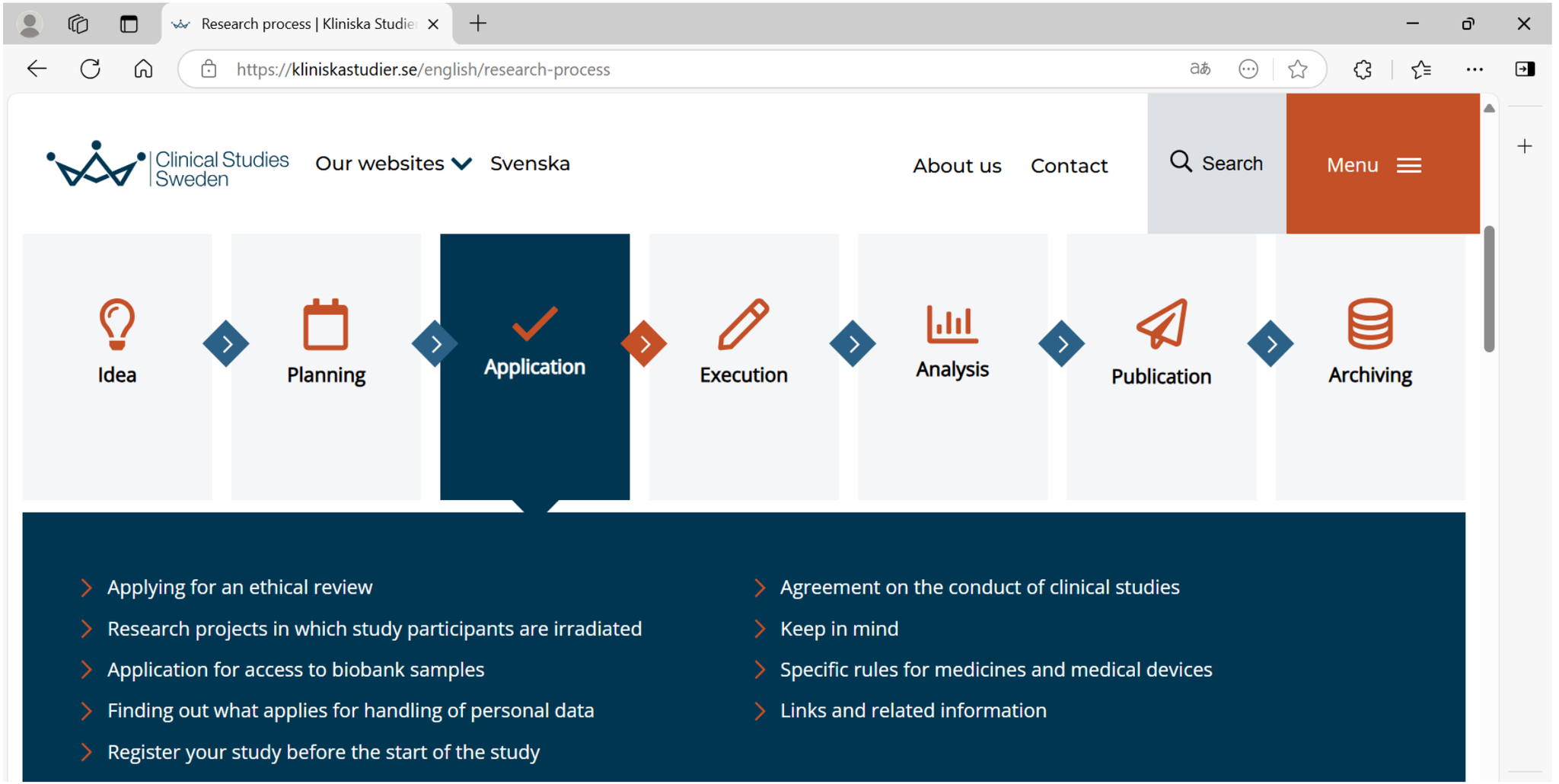
Clinical Studies Sweden

We provide research support throughout the entire research process – from idea to archiving.

Visit **Kliniskastudier.se** to take part of the research support that is available to you who conduct clinical studies in healthcare.

Clinical Studies Sweden

Clinical study research process



Clinical Studies Sweden

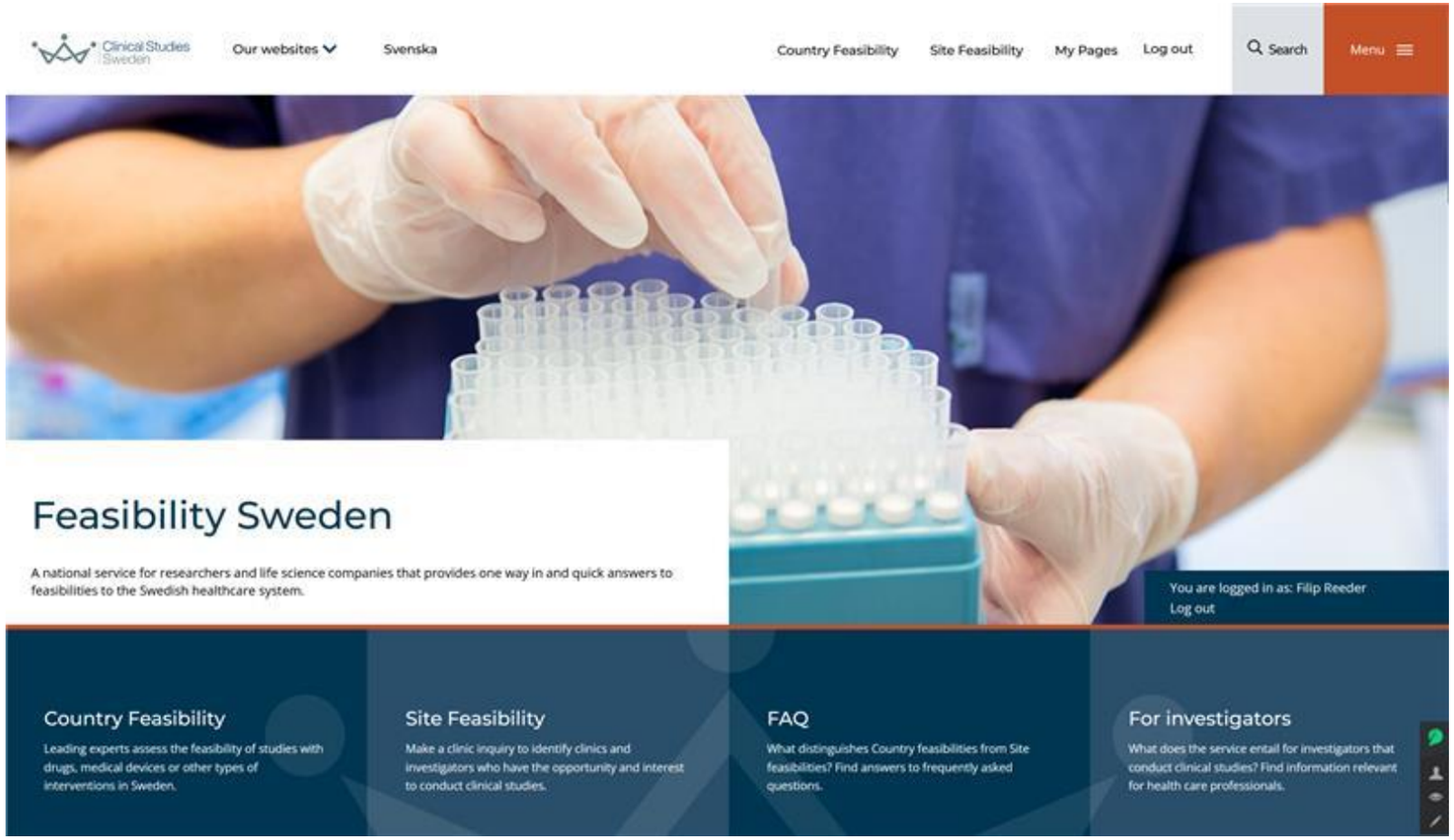
Unique Downloads 2024, Documents

- Clinical Study that is not a Clinical Trial – Checklist 714
- Trial Protocol 670
- Information for Participants 590
- Table of Contents Investigator Binder ISF 501
- Checklist for Study Agreement with In-depth Information 344
- Cost Calculation Template 336
- AE Log for Clinical Drug Trial 72
- Table of Contents Investigator Binder ISF 422
- Template for Internal Agreement: 287
- Clinical Investigation Plan (CIP) 285
- Contact Information and Timelines 257
- Investigator Responsibility - Checklist 299

Kliniska Studier Sverige

Feasibility Sweden

National service for feasibilities to the Swedish healthcare system



One request reaches all of Sweden's public healthcare – from specialist healthcare to primary care.

Clinical Studies Sweden

Feasibility Sweden

Developed with healthcare and industry

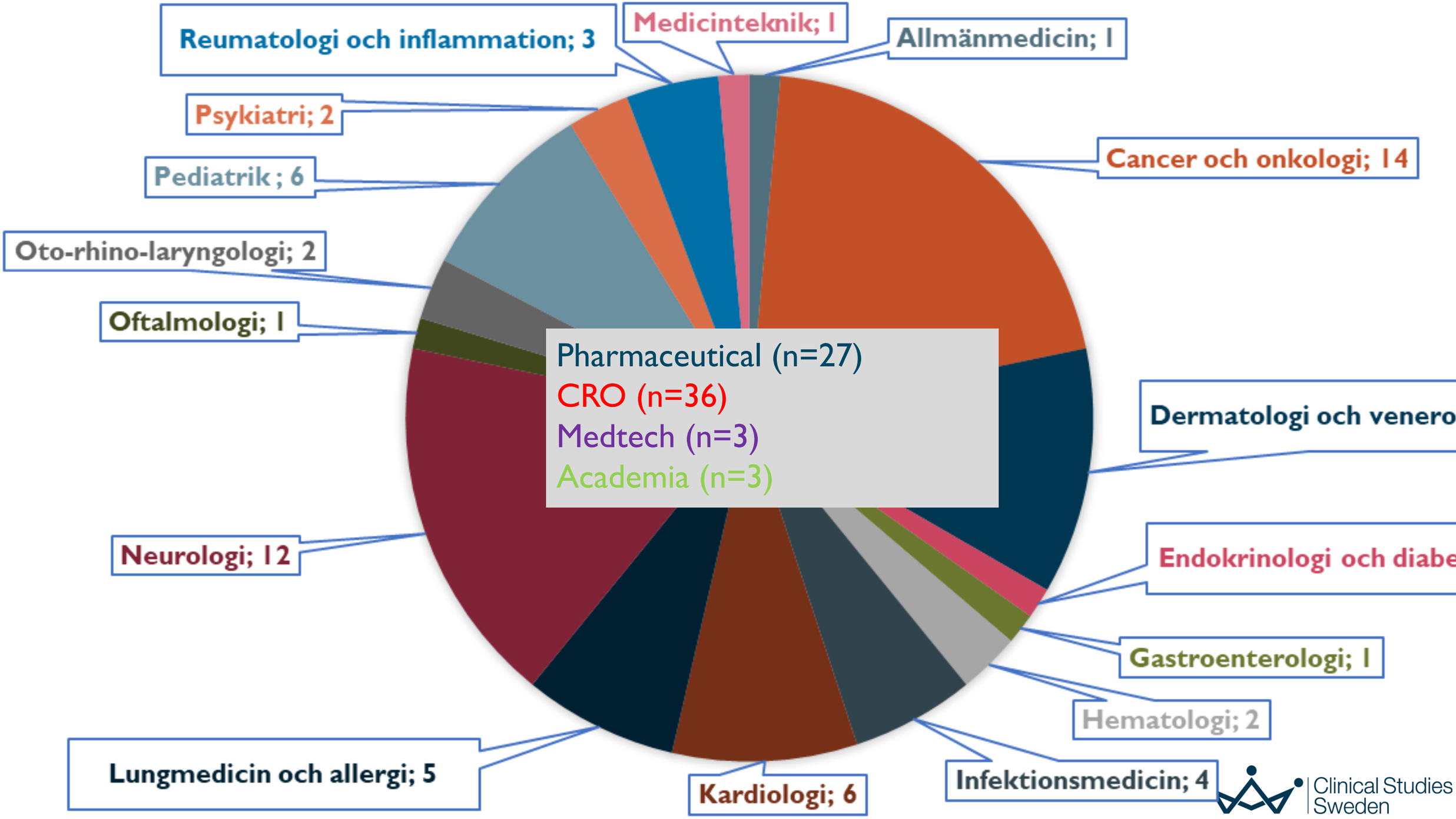
Country Feasibility

- Early requests made before decision to allocate a study to Sweden.

Site Feasibility

- Identifies clinics and investigators who are interested and able

Clinical Studies Sweden



Clinical Studies Sweden

Projects

- Agreements
- Satellitsites
- GDPR
- Training for principal investigators
- Development and marketing of Feasibility Sweden

Kliniska Studier Sverige

Current status 2025

- An established **national infrastructure for research-support** including trial units at all university hospitals and **regional coordinators** in all healthcare regions
- **Feasibility Sweden**, a national service for feasibilities to the Swedish healthcare system that reaches the entire country and all therapy areas
- **Comprehensive regulatory support** and quality-reviewed **templates and supporting documents** (several in English)
- A **comprehensive training** offer in clinical research and clinical research methodology
- Evaluation of Swedish Research Council in 2025;
  - *a robust national system for collaboration within hea* Vetenskapsrådet *ort activities*
  - *contributed to increased coordination and improved access to support for clinical studies across the country*
  - *development of common tools and processes, which particularly benefits new players in the field.*

Clinical Studies Sweden

Clinical Studies Sweden

The value our national collaboration creates over the course of a year:

91

feasibility
requests 2023

1 970

people/research projects
receive support from us

2 731

participants in
our courses

50+

Templates and
supporting documents

Clinical Studies Sweden

The National Conference on Clinical Studies

Umeå
22-23 May
2025

#kliniskastudier2025
kliniskastudier.se/konferens

Clinical Studies Sweden

Clinical Studies Sweden

Development and support of clinical studies in healthcare

Kliniskastudier.se/English

info@kliniskastudier.se

Kliniska Studier Sverige

National clinical research support networks: current status and visions

Denmark

Marianne Pihlgaard

Trial Nation
Clinical Trials Denmark

Trial Nation Denmark

Marianne Pilgaard, CEO
Trial Nation

Nordic Cooperation on Clinical Trials Infrastructure Network - Establishment Meeting
April 25th 2025

Trial Nation
Clinical Trials Denmark

Trial Nation Vision

We pave the way to a future where:

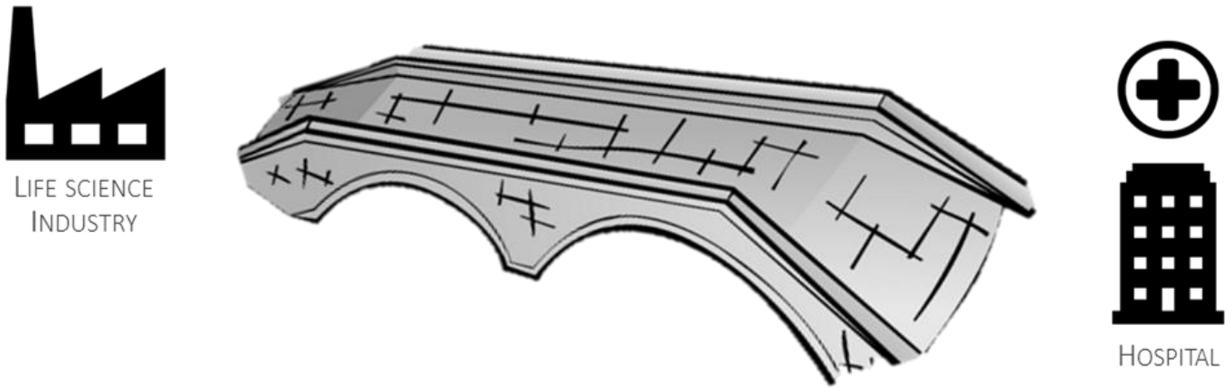
Patients enjoy stronger sustainable health
driven by fast access to cutting-edge medicine
and medical technology

Health care professionals save more lives
and promote stronger health
by always having state-of-the-art medical research
and the latest discoveries right at their hand

Through clinical research we create a better health
and wealth for Denmark

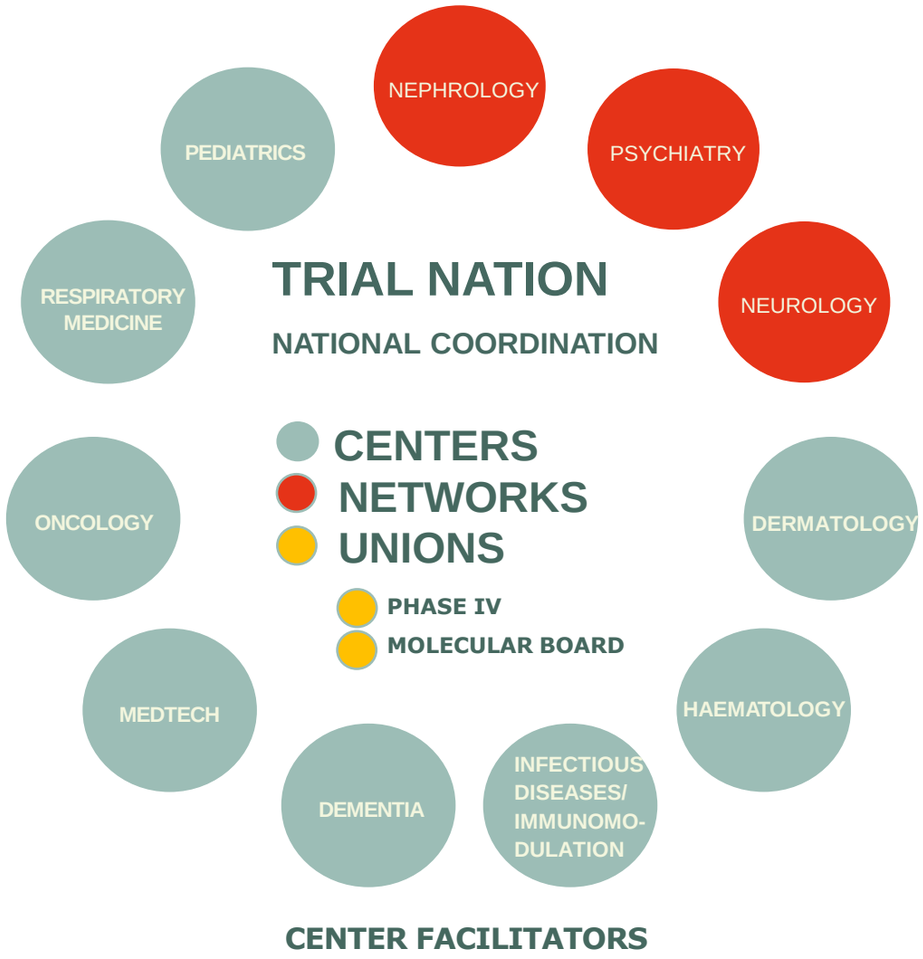
This is Trial Nation

- Trial Nation is a single entry to commercial clinical trials in Denmark– clinical infrastructure
  - Primarily publicly funded.
  - Trial Nation's services are free of charge
- Trial Nation is a prioritised stakeholder in the Danish life science strategy focussing on:
  - A public-private partnership in clinical trials
  - Framework conditions for clinical trials in Denmark
- Established to make Denmark the preferred destination for commercial clinical trials



Easy access to Clinical infrastructure

Trial Nation
Clinical Trials Denmark



OTHER DISEASE AREAS

TRIAL NATION REGIONAL PHARMA AND MEDTECH COORDINATORS FACILITATES CONTACT TO SITES IN ALL OTHER DISEASE AREAS IN ALL PARTS OF DENMARK

CONFIDENTIALITY UNDERTAKING FOR A CLINICAL TRIAL

STANDARD CLINICAL TRIAL AGREEMENT

STANDARD CLINICAL INVESTIGATION AGREEMENT – MEDICAL DEVICES

STUDY START-UP AGREEMENT

CRO - STANDARD CLINICAL TRIAL AGREEMENT

READY TO USE TEMPLATES

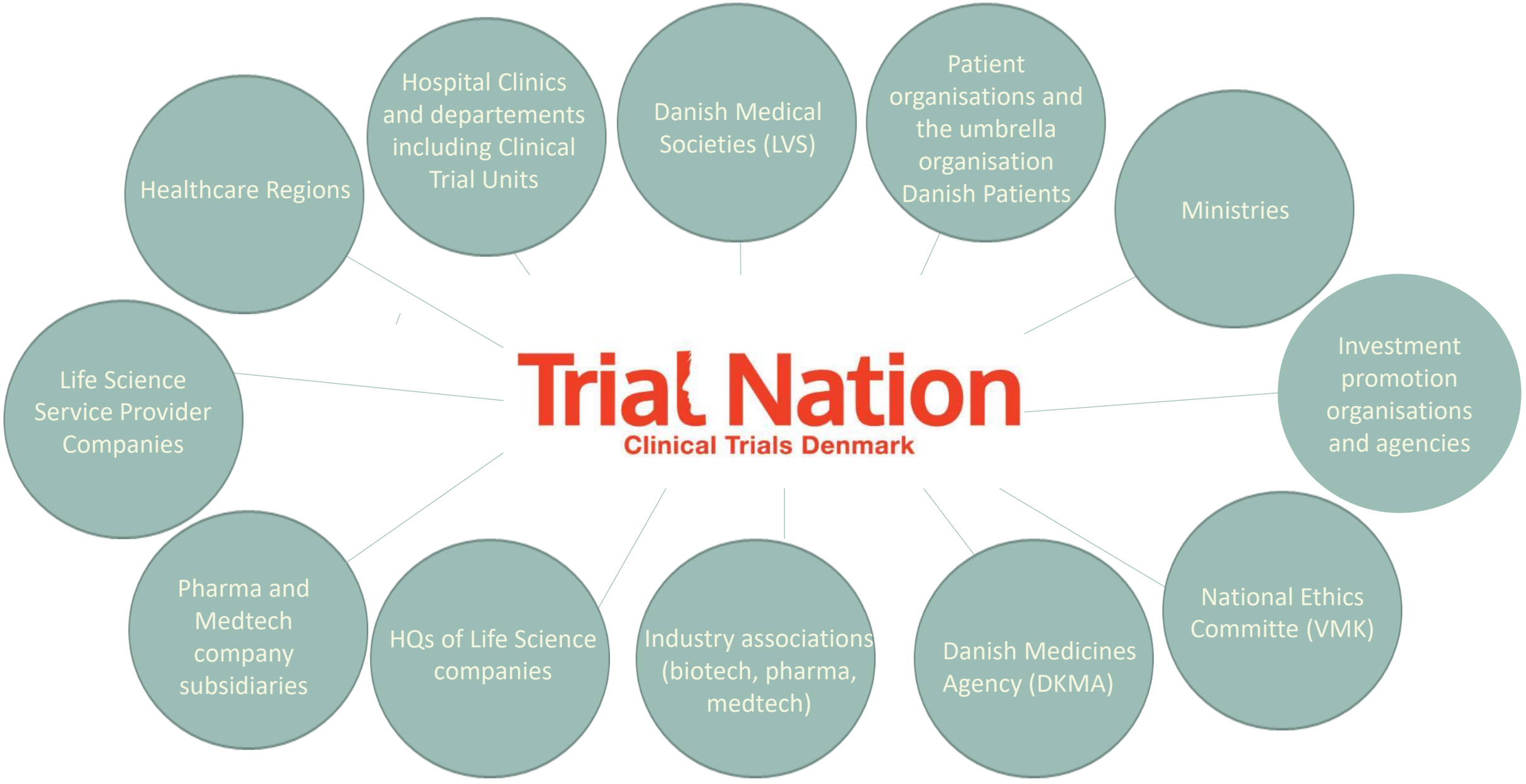
The healthcare regions in Denmark have formed a legal network within Trial Nation to ensure that the regions act as a united negotiation party for contract templates in relation to the industry.

The network provides efficient negotiation of contract templates (for CDAs, CTAs and Clinical Investigations) relating to clinical trials and investigations in Denmark. Contract templates can be used as they are or be tailored to your company. Consider using the standard templates below for the fastest possible processing time as they are pre-approved in all regions and no negotiation time is need. Please note that the Trial Nation network only negotiate contract templates, individual contracts are handled in each region. Please also note that the Trial Nation network does not provide general legal advice.

You can contact us regarding a company specific contract template (CDA/CTA/Clinical Investigation) negotiation request at legal@trialnation.dk

Strong Partnerships: The Foundation of Success!

Trial Nation
Clinical Trials Denmark



Dialogue forum with Trial Nation, Health Authorities and Industry Associations

- Exchange of information and actions relevant for clinical trials/investigations in Denmark.
- Discussion on effective implementation on new clinical trial/investigation related regulations.
- Discussions of issues related to start-up and conduct of clinical trials/investigations.
- Work with the framework for innovation in clinical trials.
- Coordination of common information and training activities.

Trial Nation
Clinical Trials Denmark

Trial Nation

Get in touch:

contact@trialnation.dk

www.trialnation.dk

Follow us on LinkedIn

National clinical research support networks: current status and visions

Finland

Mia Bengtström

Clinical trials in Finland – Status report

22.4.25

Identified challenges in the current system*

Client (Pharmaceutical company /Health tech)

1. **Contract and budget negotiations** are lengthy and must be done separately with each hospital. This significantly slows down the processes.
2. **Feasibility process** fragmented, unpredictable, no time limits.
3. There is a shortage of **research physicians** in several therapeutic areas and finding them is challenging.
4. Companies that **do not have ready-made contacts** may have difficulty launching studies.
5. Finland **lacks system performance indicators** (e.g. speed and reliability), which are essential in international competition and marketing.
6. Finland is **slow to introduce new innovative treatments** and Finland is dropping out of studies where the inclusion requirement is treatments that are not yet used in Finland.

Producers (Wellbeing counties and HUS)

1. **Research infrastructure** (research structures and contract structures) is inadequate and organized in a patchy manner in several welfare areas.
2. There **is no clear CTO** activity and resourcing in all wellbeing areas. In some cases, research has to be refused due to a lack of resources.
3. It is **difficult to manage demand fluctuations** from a resourcing perspective; there is no overall picture of demand.
4. **Financial incentives are unclear** for both the organization and researchers.
5. The current **funding system's incentive** to conduct research is unclear or non-existent.
6. **Building cooperation** between different therapy areas and wellbeing areas is challenging in places and is still in the process of being built.

*Based on interviews

CTO = Clinical Trial Office.

Expectations from the new cooperation model*

Client (Pharmaco/Health tech)
“Speed, predictability and reliability”

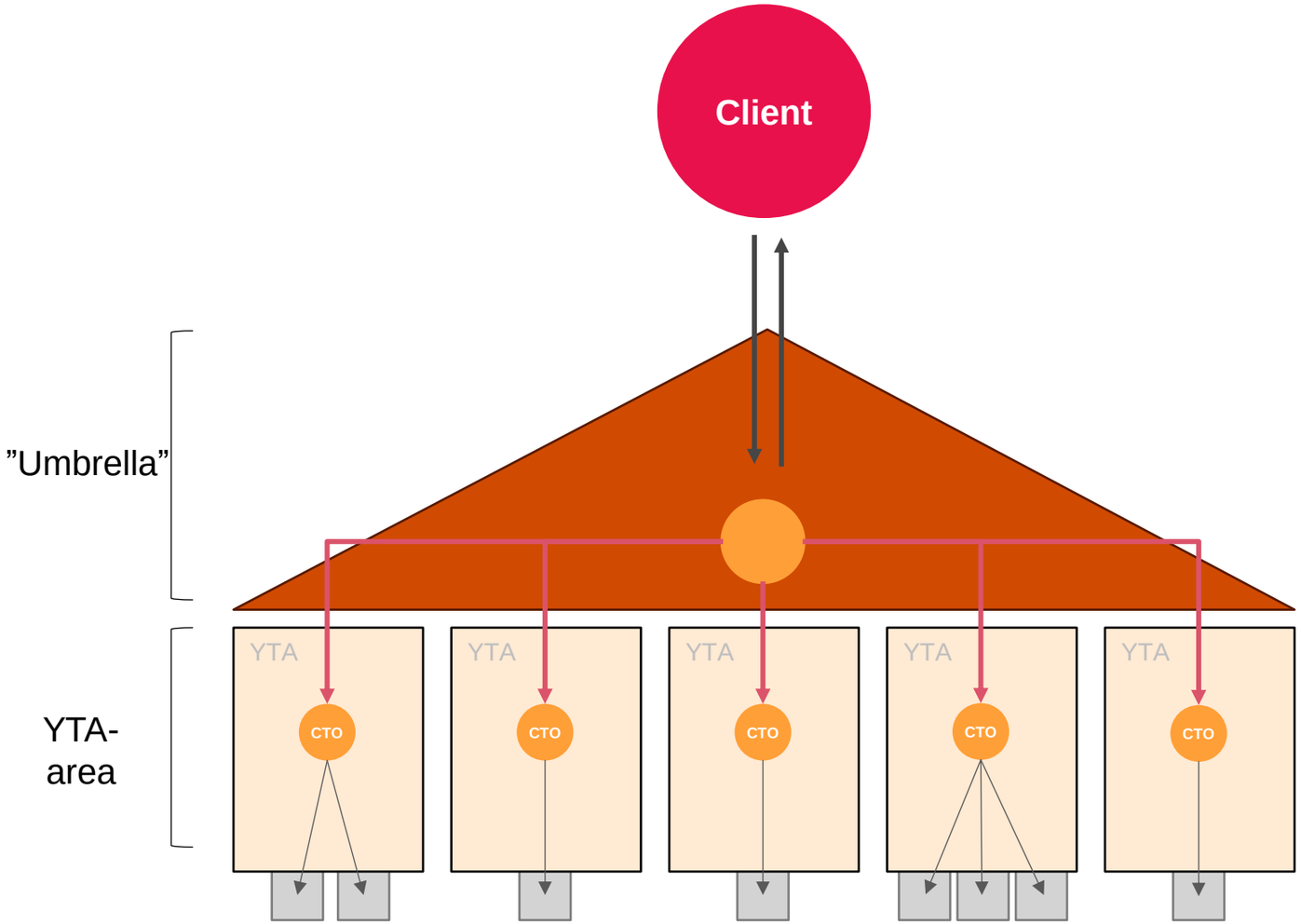
1. **Defined time limits** for feasibility studies that are adhered to.
2. **Sticking to the originally agreed time limits and patient numbers**.
3. **The quality must be like the competitors**.
4. For the Finnish system, there should be **clear performance indicators** (for example, feasibility speed, average time for contract negotiations, etc.). The indicators are monitored by pharmaceutical companies and the choices are largely based on previous performance.
5. **Starting with well-functioning structures that are already in place** and understand that the process is iterative.
6. The new structure must **not create additional costs** for companies

Producer (Wellbeing area and HUS)
“Resources”

1. The new cooperation model should be built in such a way that **existing structures are not dismantled**.
2. For the new structure to function smoothly, the **incentives** for welfare areas and researchers should be identified as a significant factor and be in place.
3. Cooperation with companies should not negatively affect **universal funding of wellbeing areas**.
4. The system should be up-to-date with **EU regulations** and compatible with legislation.
5. **Cooperation areas (YTA) should be taken into account in the new structure**. YTA has a legal obligation to act as a hub for research activities in the regions.

*Based on interviews

The target state presented in the project is based on speed, predictability and reliability

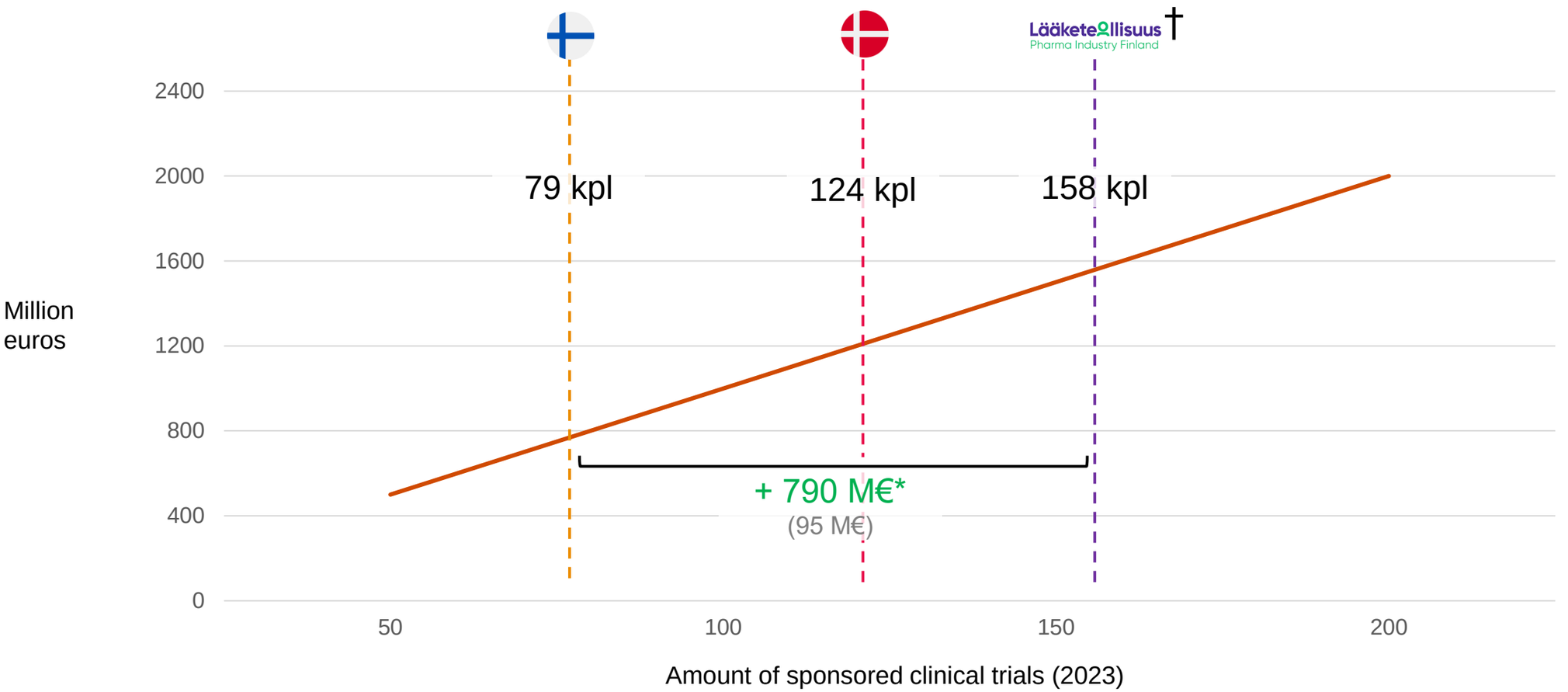


- The **customer** sees the situation as a coordinated whole. New customers can easily enter the market through one clear “door”. The customer can trust that Finland will operate within the agreed timeframes.
- The **umbrella** organization has a clear understanding of the demand for Finland and the bottlenecks facing clinical trials. The umbrella organization’s task is to raise Finland to the crest of the wave in those areas where Finland’s competitiveness is believed to be/potentially top-notch. The organization’s task is to integrate the centers of excellence to work together effectively.
- **Clusters** are centers of expertise that are built in collaborative areas. The cluster provides the necessary resources and, in the initial phase, strengthens in particular those areas where there is already the ability and readiness to develop operations. The clusters work in close cooperation with the umbrella organization, through which up-to-date information on demand is transmitted. The cluster is resourced so that it can deliver queries related to the feasibility process within defined time limits to the umbrella organization, which collects the responses and delivers them to the customer.

CTO = Clinical Trial Office.

Client contact | Fintrials coordination | CTO coordinates

Financial potential in sponsored clinical trials (Lääketeollisuus ry investment promise)



† Lääketeollisuus ry investment promise 2025

* Increased societal value and direct benefit of initiated commercial drug trials in brackets

Lääketeollisuus ry raportti 2024
IQVIA ja EFPIA-VE: Assessing the Clinical Trial Ecosystem in Europe, August 2024
Lääketeollisuus ry ja Esior Oy: Selvitys lääketutkimuksen yhteiskunnallisesta arvosta, 11.06.2024.
Lääketeollisuus ry. (2025). Lääketeollisuuden arvolupaus: Tavoitteena miljarditason investoinnit Suomeen vuoteen 2030 mennessä. Julkaistu 21.3.2025.

National clinical research support networks: current status and visions

Island

Halla Sigrun Arnardottir

LANDSPÍTALI

Clinical Trials in Iceland: Current status, challenges and future vision

Halla Sigrún Arnardóttir
Project Manager, Clinical Research Center, Landspitali

Nordic meeting in Oslo 25.April 2025

LANDSPITALI
UNIVERSITY HOSPITAL

Icelandic Health Care System

Icelandic population
- 384.000 (Jan. 2024)
- 247.000 in the capital area

Good clinical outcomes in comparison to other OECD nations

Health sector counts for 9,3% of GDP

- **One university hospital**
- **One teaching hospital**
- **Several small rural hospitals**
  - primary care
  - nursing homes
- **Primary health care centres**
- **Private practices**

LANDSPÍTALI

Clinical trials in Iceland – CTIS April 2025

Clinical trial sites

- Landspitali 19 trials
- Private practices 4 trials
- (one rejected and new application sent under new EU CT number)
- Total: 24 trials

Clinical trials at Landspitali – in collaboration with:

- Nordic university hospitals (8)
- Pharmaceutical companies (8)
- Private Hospital/Research Institution in EU (2)
- Landspitali sponsor (1)

LANDSPÍTALI

Landspítali University Hospital

Only University Hospital in Iceland

A third of the population served in 2023

40 medical specialities

Medical speciality training abroad

- Sweden, Norway, USA, UK, The Netherlands…

Selected patients transferred abroad

- Some heart surgery, some stem cell treatments, and solid organ transplants (excl. renal transplants)

6.600 employees

2.000 students

Clinical Research Center at Landspitali (2010)

- Clinical trials are conducted in various departments at the hospital
- Innovation work in collaboration with deparatment of Developement (Auðna-TTO, Nordic Proof)
- Domestic collaboration f.ex. Decode Genetics, Icelandic Heart Association, Cancer registry
- Nordic collaboration, registries, research groups, NORM, NUHA, Nordic proof f.ex.
- International collaboration, EU funded programs, NIH funded programs,

LANDSPÍTALI

Clinical Research Center

- Feasibility assessment
- Study documents, ICF etc
- Contracts
- Legal issues, intellectual property rights
- Application procedure (CTIS)
- GCP training

- Financial matters, study fee and grants
- Statistical support
- Preparation of audits and inspections
- Registration in open database

What makes Iceland unique for Health Research

- Genetic Research Infrastructure
- Nationwide Health Registries
- Single Tertiary Care Center (Landspitali)
- Feasibility of Real-world evidence and Precision Medicine
- Public trust in healthcare and research institutions
- Capacity for Translational Research and Innovation

Future vision and challenges

Challenges

- Decrease in Clinical Trials, increased complexity
- Heavy workload, shortage of staff
- Healthcare technology, AI
- Growing population of non- Icelandic speakers - inclusion
- GDPR – collaboration outside EU/EEA

Future vision

- New hospital and CRC
- Infrastructure supports research !
- New Science Policy – action plan
- Funding for development of the eHR system for pragmatic studes
- Nordic collaboration remains a cornerstone

Established networks for Nordic collaboration, a brief overview of objectives, successes and bottlenecks

Nordic Trial Alliance

Ole Alexander Oppdalshei

Nordic Trial Alliance

An initiative to support Nordic cooperation in clinical research

Ole Alexander Opdalshei

The Nordic Trial Alliance Project

What

- A strategic activity funded within the framework of the Nordic Council of Ministers (2013-2016) and NTA 2.0 (2017-2019). Norway being a driver.
- Co-funded by NordForsk who also acts as secretariat
- In total appr. 9 M NOK (excl. research project funding)

Aim

- to strengthen clinical research in the Nordics, and especially clinical multi-centre trials

Why a Nordic initiative on clinical trials?

- Back in 2012, there was a worrying trend with declining number of clinical studies in the Nordics
- The regulatory situation made it difficult for academic studies
- Barriers impeding academia-industry-collaboration
- Companies had difficulties finding researchers and trial sites
- The potential in Nordic multi-centre studies not supported
  - Nordic patients didn't know how to find on-going clinical studies
  - Barriers for cross-border recruitment of patients
- Lack of funding for Nordic projects

norden

Det framtida nordiska hälsosamarbetet

Bo Könberg

DAGENS Medisin

DM Debatt DM Event DM Jobb DM + Logg inn

ENIGE: Helseministerne Juha Rehula og Bent Høie inviterer sine nordiske kolleger med på helseforskningssamarbeid. Et felles brev ble undertegnet på et møte i Amsterdam mandag denne uken. **Foto:** HOD

Nordisk samarbeid skal gi flere kliniske studier

Den norske og finske helseministeren tar initiativ til økt nordisk forskningssamarbeid. Målet er flere kliniske studier i Norden.

Målfrid Bordvik

PUBLISERT 19.04.2016 - 14:50

Activities funded or organized by NTA (selection)

- Annual Stakeholders meetings
- Grants for establishing Nordic networks
- Grants for Nordic workshops and conferences
- Grants for Nordic collaborative activities
- Open calls for Nordic research projects (funded separately)

- Website

NTA Pilot Projects 2013

Early on in the first NTA project, the NTA Board identified eight areas of immediate need for coordinative clinical research activities. In order to gain momentum on the road towards a common Nordic clinical research market, a call for Nordic implementation activities were opened 2013 and five activities funded:

- Collaboration on ethical review of clinical research in the Nordic countries
- Collaboration between Industry and Academia
- Monitoring of Clinical Research
- Transparency and Registration
- Nordic network for medicines for children – NordicPedMed

2016 Strategic Implementation Projects

NTA announced calls for strategic implementation projects with the aim to increasing Nordic collaboration by reducing cross-border barriers. Nine activities, mostly networks and workshops, were funded:

1. *Workshop on Cross border participation in clinical trials in the Nordic region*
(Project Leader Steinar Aamdal, Oslo University Hospital)
2. *Harmonised Nordic Ethical Evaluation of Clinical Trials*
(MProject Leader Mika Scheinin, Hospital District of Southwest Finland, Research Services)
3. *Nordic Monitoring Network*
(Project Leader Birgitte Vilsbøll Hansen, GCP unit Copenhagen University Hospital, Denmark
4. *Establishing a Nordic network for clinical trials in children – NordicPedMed Stage 2*
(Project leader Pirkko Lepola, Helsinki University Hospital)
5. *Nordic Conference on Real-World Data*
6. *Nordic Hotspot for Life Science*
7. *Nordic Network on antimicrobial multi-resistance research*
8. *Workshop on Nordic Pragmatic Clinical Trials*
9. *Conference on Collaborative Nordic Use of Health Care Quality Registries*

2018 Nordic Strategic activites

In November 2018, NTA opened a call for proposals for strategic activities aiming to promote Nordic cooperation within clinical research. Funded activities should have a vision to move Nordic collaboration within a certain area forward and a concrete outcome that will enhance Nordic clinical research cooperation. Three activities were funded with up to 300 000 NOK each.

1. *Nordic monitoring network*
(Project Leader: Birgitte Vilsbøll Hansen, Copenhagen University Hospital, Denmark)

2. *Nordic PedMed Stage 3 – Nordic paediatric medicine cooperation*
(Project Leader: Pirkko Lepola, Helsinki University Hospital)

3. Nordic Myeloma Study Group
(Project Leader: Anette Juhl Vangsted, Rigshospitalet, Denmark)

2019 Nordic Strategic Activities

During spring 2019, NTA opened a call for proposals for strategic activities aiming to promote Nordic cooperation within clinical research. Funded activities should have a vision to move Nordic collaboration within a certain area forward and a concrete outcome that will enhance Nordic clinical research cooperation. Six activities were funded with up to 300 000 NOK each.

1.*Strategic workshop of the borderline research between traditional interventional clinical trials RCT and Real World Evidence / Register studies*
(Project Leader: Marina Bengtström, PIF, Finland)
2. *Nordic Alliance in Faecal Microbiota Transplantation (FMT)*
(Project Leader: Christian Lodberg Hvas, Aarhus University Hospital, Denmark)
3. *Nordic network for emergency department pain management*
(Project Leader: Anders Moellekaer, Aarhus University Hospital, Denmark)
4. *NORdic uroTHelial cancer REsearch Group – NORTH-REG network*
(Project Leader: Jørgen Bjerggaard Jensen, Aarhus University Hospital; Denmark)
5. *Nordic Anal Cancer Network*
(Project Leader: Karen-Lise Spindler, Aarhus University Hospital, Denmark)
6. *Nordic EUPATI workshop (patient network)*
(Project Leader: Mirjami Tran Minh

Association of Cancer Patients in Finland & EUPATI Finland)

2020 Nordic COVID-19 activities

In April 2020, NTA invited proposals for activities aiming to promote Nordic cooperation related to COVID-19 research. Activities should strengthen Nordic collaboration and knowledge transfer, with a concrete outcome that will enhance Nordic clinical research cooperation and contribute to the global knowledge related to COVID-19. Four activities were funded with up to 500 000 NOK each:

1.*Establishing the Nordic node of the COVID-19 host genetics initiative*
(Project Leader: Andrea Ganna, FIMM, Finland)

2. *Is severe COVID-19 associated with altered long-term cognitive function? (ASSESS-SHOCK3-COVID)*
(Project Leader: Johanna Hästbacka, University of Helsinki, Finland)

3. Merging the four Nordic ICU registries for epidemiological research of critically ill COVID-19 patients
(Hans Flatten, Haukeland University Hospital, Norway)

4. *ACE/ARB-COVID-19 – A Nordic population registry study of ACE inhibitors/ARBs and SARS-CoV-2 infection severity*
(Marte Helene Bjørk, University of Bergen, Norway)

2021 Nordic Collaboration Activities

NTA invited proposals for activities that promote Nordic co-operation on clinical research. More specifically, the purpose of this call was to support activities that aim to build a Nordic platform for participation in upcoming activities at European level, e.g. within Horizon Europe and EU4Health. Activities should strengthen Nordic collaboration and knowledge transfer and deliver concrete outcomes that enhance Nordic clinical research co-operation. Five projects were funded with up to 400 000 NOK each.

1. *The LD-VenEx clinical trial for Acute Myeloid Leukaemia*
(Project Leader: Bjørn Tore Gjertsen, Oslo University Hospital, Norway)
2. *NorEpiNet*
(Project Leader: Kaja Selmer, Oslo University Hospital, Norway)
3*.The Nordic SBRT study group – infrastructure and clinical research*
(Project Leader: Karin Lindberg, Karolinska University Hospital, Sweden)
4*. The Nordic Precision Cancer Medicine Trial Network*
(Project Leader: Kjetil Taskén, Oslo University Hospital, Norway)
5*. Establishment of Network for Nordic Pediatric Clinical trial Units*
(Project Leader: René Mathiasen, Rigshospitalet, Denmark/NordicPedMed)

Nordic Projects on Paediatric Cancer Research 2018

- To support Nordic researcher projects in cancer medicine or expansion of ongoing national projects into Nordic ones
- Establish Nordic competence networks within clinical research on paediatric cancers
- The call was a joint effort by NordForsk, the Norwegian Cancer Society and the Research Council of Norway. Each project received up to 10 MNOK. Three projects were funded.

Nordic ALLSTAR
Project Leader: Thomas Leth Frandsen, Rigshospitalet, Copenhagen
(DK-FIN-NO)

NOPHOmatch
Project Leader: Karsten Nysom, Rigshospitalet, Copenhagen
(DK-FIN-NO-SE)

ALLTogether - a European treatment protocol for children and young adults with acute lymphoblastic leukaemia (ALL)
Project Leader: Mats Heyman, Karolinska University Hospital, Stockholm
(ALL Nordic countries)

Lessons learned

- Strong engagement and interest in Nordic collaboration
- An understanding for the need and potential for collaboration
- Several good initiatives and projects

- Lack of a long-term strategy
- Demanding to coordinate the various initiatives
- How are projects taken forward?

nta.nordforsk.org

ole.alexander.opdalshei@kreftforeningen.no

NordForsk

NORDIC • TRIAL • ALLIANCE

Established networks for Nordic collaboration, a brief overview of objectives, successes and bottlenecks

Nordic Molecular Tumor Board

Martin Højgaard

Nordic Molecular Tumor Board

Oslo – 25th April 2025

About and disclosures

Martin Højgaard

Clinical oncologist –

Phase1 Unit, Dept. Of Oncology – Rigshospitalet, Copenhagen - Denmark

Representing on behalf of the 'Nordic Molecular Tumor Board' an *academic collaboration between health care professionals and academics in the Nordic countries (Iceland, Finland, Sweden, Norway and Denmark) with an interest in early phase oncology trials.*

Disclosures:

Personal:

Principical investigator in +10 phase1/2 oncology trials

ESMO DOI# 00016079

Institutional:

The Phase1 Unit, Rigshospitalet has more 45 ongoing sponsored clinical trials

https://www.rigshospitalet.dk/english/research-and-innovation/units-and-groups/phase-1-unit/Pages/default.aspx

A Nordic Molecular Tumor Board

- Background
  - Previously some activity in NORDIC-NECT (co-operation between phase1 units in DEN-NOR-SWE-FIN)
  - Increasing data collaboration in DRUP like trials (FINPROVE, IMPRESS Norway, PROTARGET, FOCU.SE)
  - Co-operation in EU projects (PRIME-ROSE; PCM4EU)
  - Cross border referrals in clinical trials dependent on personal relations

IMPRESS NORWAY

ProTarget

FINPROVE

FOCU·SE

Nordic Molecular Tumor Board

Increasing molecular profiling activity

More targets uncovered

Increased need for referral to biomarker specific trials/compassionate use programmes etc

Increased need for knowledge exchange and networking

- Clinicians
- Trial administrators
- Diagnostic dept.
- Researchers
- Regulatory bodies

Image credit: ngc.dk

2. Nordic Molecular Tumor Board

Creating a sustainable academic network

Mission statement

NMTB’s purpose is to facilitate exchange of knowledge on ongoing and upcoming early phase 1-2 oncology trials for adult solid tumors. Phase 3 trials with select molecular alterations as well as early access / compassionate use programs can also be discussed.

Independent construction

2. Nordic Molecular Tumor Board

- Sharing information on new/upcoming molecular targets
- Improve networking for cross border referrals
- Highlight specific trials with rare molecular targets for cross border patients

- Share experiences on organizing national molecular tumor profiling infrastructure and site capabilities
  - Relevant for ongoing and upcoming EU projects
  - Relevant for potential sponsors
- Established national and multi-state MTB infrastructure important in attracting clinical trials
- Forum for discussing selected patient cases

2. Nordic Molecular Tumor Board

Late spring 2024

Formal inquires made to relevant stakeholders in Nordic count

The following persons coordinating for each country:

- Iceland (Sigurdis Haraldsdottir) -> Gudbjörg Jónsdottir
- Sweden (Ana Carniero)
- Norway (Gro Live Fagereng)
- Finland (Katriina Jalkanen)
- Denmark (Martin Højgaard)

Organization

Monthly virtual meetings (last Thursday 1530-1615 CET)

Agenda template

- **1 Welcome and introduction**
- **2 Trials of relevance for cross border patients in the Nordics** (countries presenting in alphabetical order)
- **3 Selected patient cases, maximum 1 pr country.** No patient specific data (name, d.o.b or similar)
- **4 Upcoming molecular targets of interest** (e.g. upcoming trials)
- **5 Item of the month**
- **6 Miscellaneous**
- **7 Next meeting**

So far

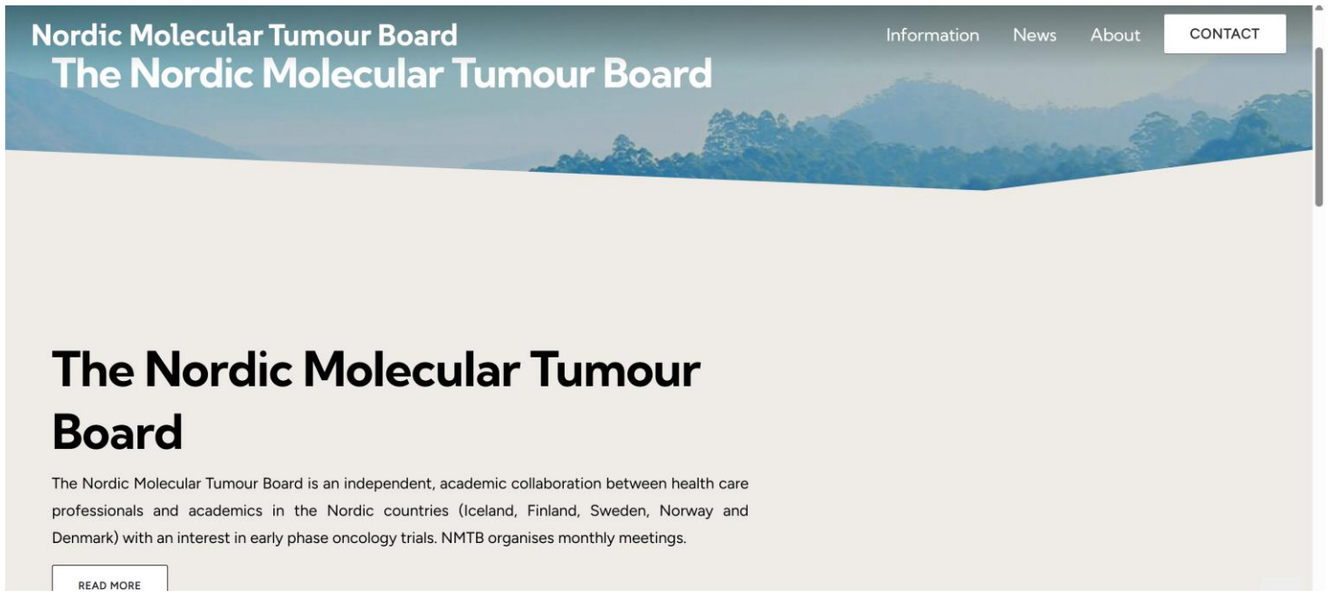
7 meetings since September 2024

Website for information on the project

+70 individuals in the network

Relevant trials circulated monthly allowing for direct access to principal investigator

Sponsors very positive – highly relevant for attracting trials to the region



Country	Target/diagnosis	Trial	Contact
Denmark	MAGEA4 expression, synovial sarcoma, myxoid/round cell liposarcoma	CDR-404	iben.spanggaard.01@regionh.dk
Denmark	H3K27M-mutant diffuse glioma	ONC201	annette.kodahl@rsyd.dk
Denmark	HER2 mutated solid tumors (excl NSCLC)	panSOHO	martin.hoejgaard@regionh.dk
Finland	NF2/LATS1/LATS2, YAP/TAZ fusions	TEADES	katriina.jalkanen@hus.fi
Norway	FGFR3 mutations / fusions	Loxo-FG3-22001	uxtour@ous-hf.no
Norway	MSI-H/dMMR after ICI	CHRO761A12101	uxtour@ous-hf.no
Sweden	RCC stg V renal failure and dialysis	Oncorella	luigi.depetris@regionstockholm.se
Sweden	BRAF-fusions (and BRAFV600E rare indications, prior BRAFi naive)	FORE Plixorafinib	luigi.depetris@regionstockholm.se
Sweden	NSCLC with HER2 TKD mutations, including HER2 Ex20 insertions	CERTIS1	luigi.depetris@regionstockholm.se

More about us

Website: www.nordicmtb.no

Join the mailing list and receive invites for monthly meetings and trial overview

Martin.hoejgaard@regionh.dk

www.linkedin.com/in/martinhojgaard

Contact us:

- Ana Carneiro ana.carneiro@med.lu.se (coordinating for Sweden)
- Gro Live Fagereng gfageren@ous-hf.no (coordinating for Norway)
- Katriina Jalkanen katriina.jalkanen@hus.fi coordinating for Finland
- Gudbjörg Jónsdottir gudbjons@landspitali.is coordinating for Iceland
- Martin Højgaard (coordinating for Denmark) martin.hoejgaard@regionh.dk

Established networks for Nordic collaboration, a brief overview of objectives, successes and bottlenecks

Nordic Proof

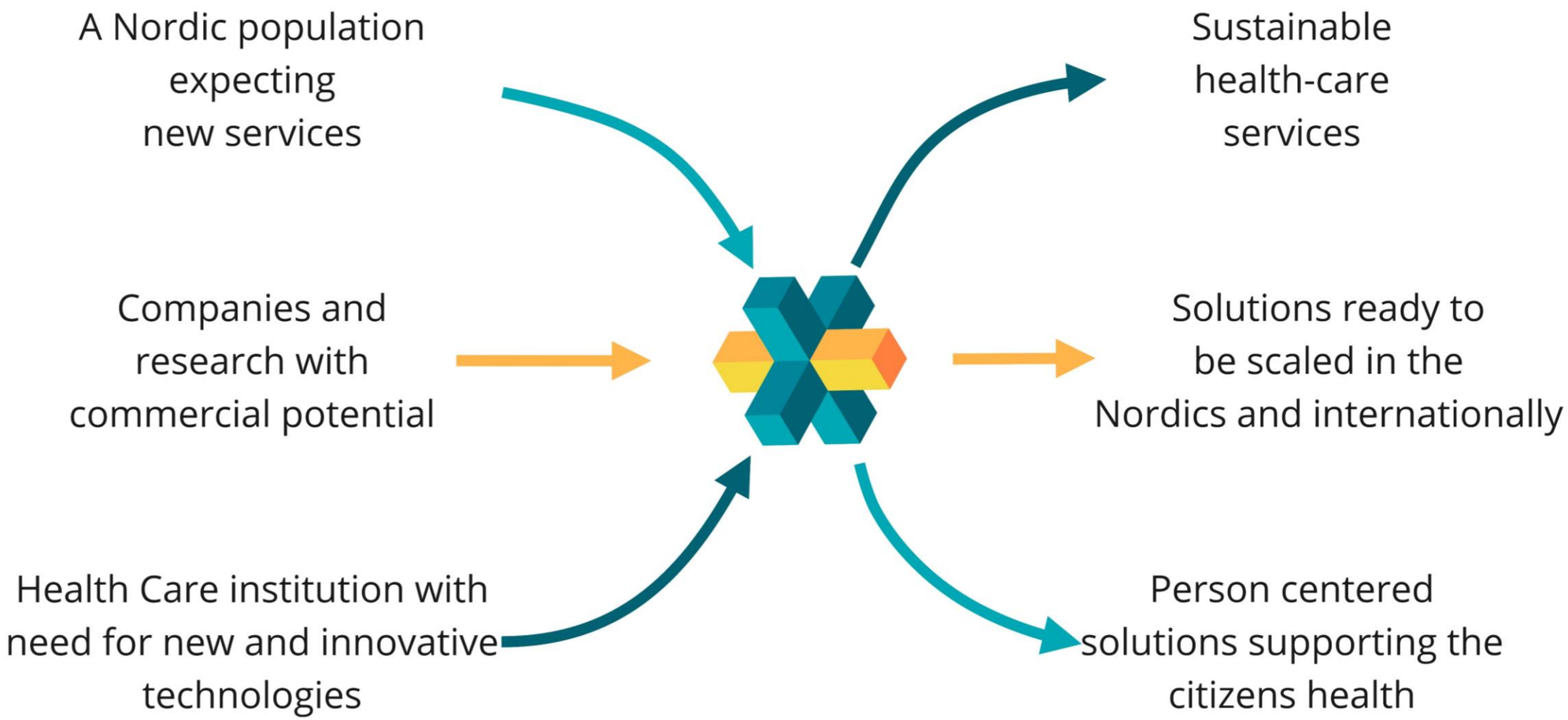
Bent Håkon Lauritzen

NordicProof

Testing solutions for world class healthcare

10 years of partnership 2015 - 2025

Objective Nordic Proof



NordicProof

12 Partners Across the Nordics

Finland

OULU HEALTH LABS

HEALTH CAMPUS Turku

HEALTH PROOF HELSINKI

XAMK Active Life Lab

Norway

Oslo University Hospital
The Intervention Centre

NORWEGIAN SMART CARE LAB

VESTRE VIKEN

SUNNAAS REHABILITATION HOSPITAL

Denmark

AARHUS KOMMUNE

Sweden

SAHLGRENSKA SCIENCE PARK

INNOVATION SKÅNE

Island

LANDSPÍTALI

Nordic Proof – how do we operate

Partnership agreement regulating obligations and rights
Norway Health Tech appointed as Coordinator

The partners' services and capacity are presented collectively to the industry in the Nordic region and selected regions outside the Nordics.

Online meetings every 14 days to work on inquiries
Physical partner meetings twice a year – strategic development of the network

Companies pay for services – signed contracts

NordicProof

Some figures from 2024

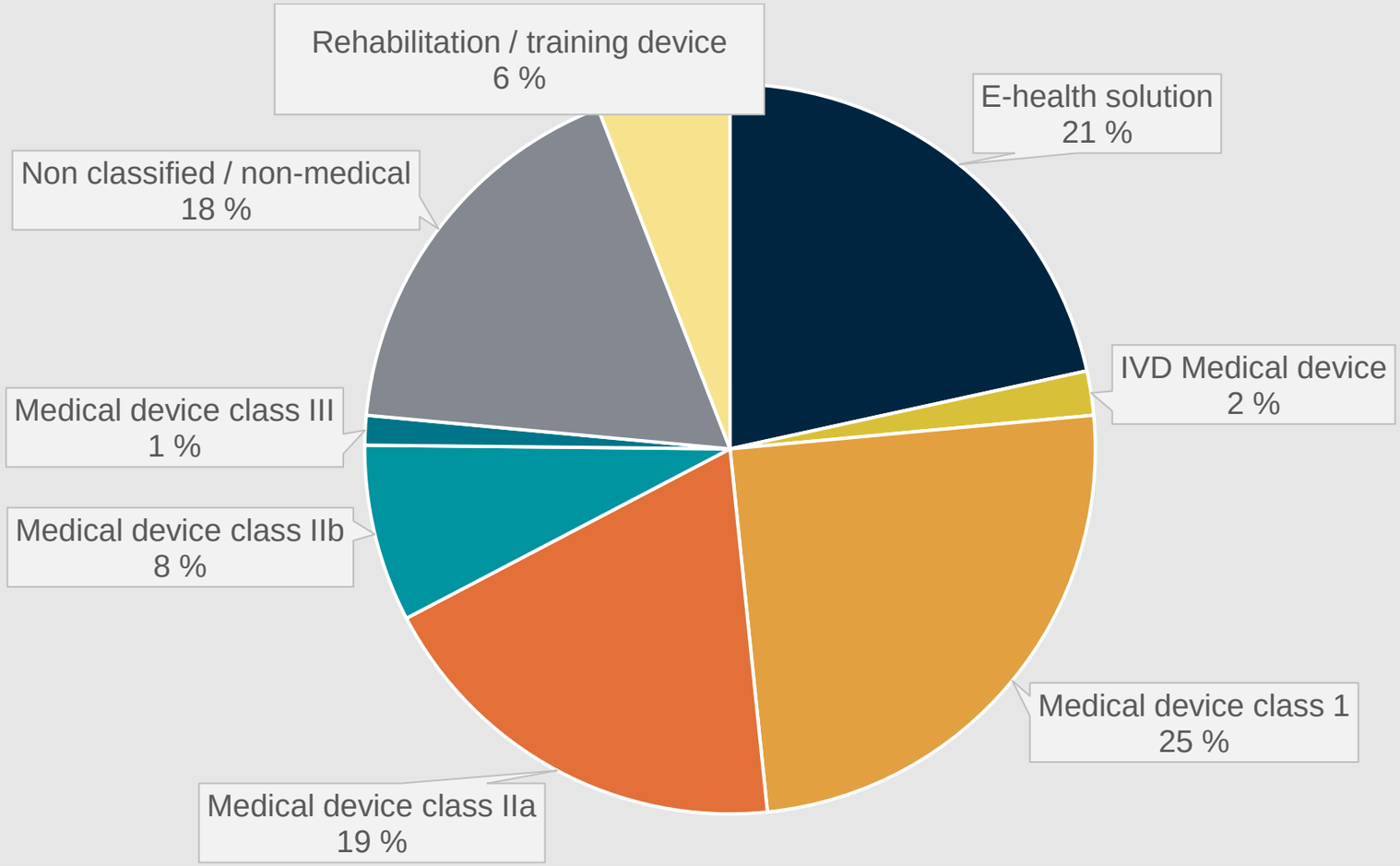
215 test inquiries screened and currently in process

91 signed contracts between industry and Nordic Proof partners

144 test inquiries from Nordic companies

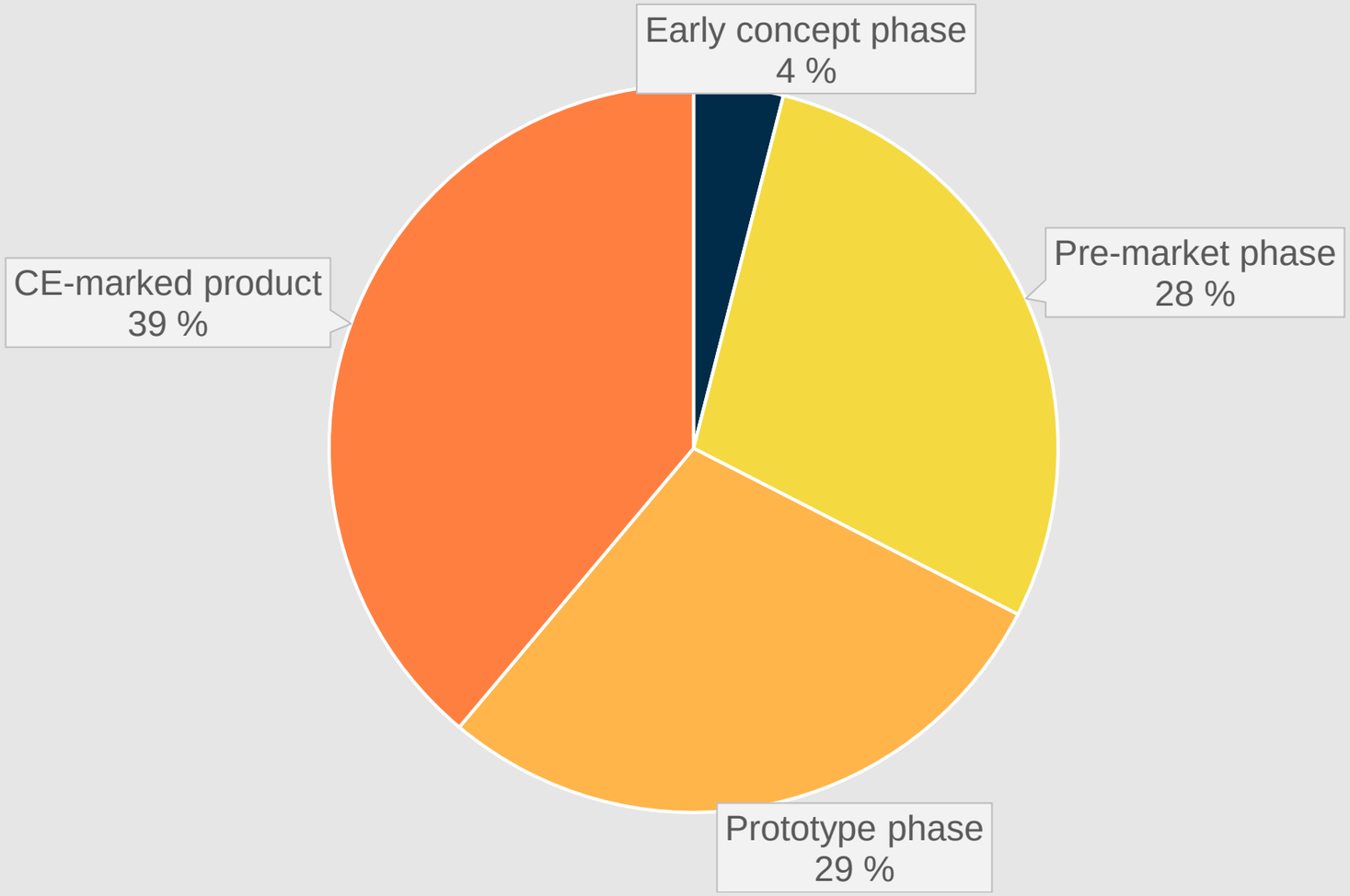
Test inquiries received from **17** different countries across the EU and the UK

Different types of technologies



NordicProof

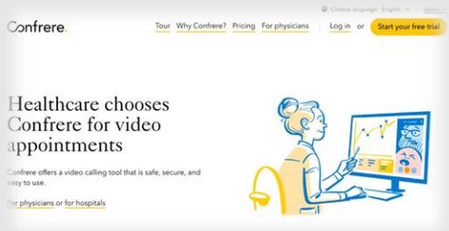
Product development phase



NordicProof

SUNNAAS REHABILITATION HOSPITAL

User test in simulated environment
Functionality, user friendliness, clinical relevance, hygiene and safety.



Research
Clinical studies

Workshop
- «Reality check» of idea or prototype with clinical staff.
- Important feedback in the development fase.

NordicProof

User testing in clinical environment
Functionality, user friendliness, clinical relevance, hygiene and safety.

Innovation → Development → Research

Njord MedTech: Patient transfer device

test case example.

The company collaborated with multiple testbeds, including:

- Norwegian Smart Care Lab
- Stavanger University Hospital
- Sandnes Education and Research Center (SEARCH)
- Oulu Health Labs

NordicProof

Bottlenecks

Generic problems Medtech/e-health

- Fragile companies (startups and non funded scale ups)
- Growing complexity and cost to comply with regulatory processes
- R&D projects vs commercial pilots

Need for Nordic collaboration

- Keep projects in the Nordics
- Attractiveness and awareness - international industry
- Bring down barriers for scaling of new solutions in the Nordics

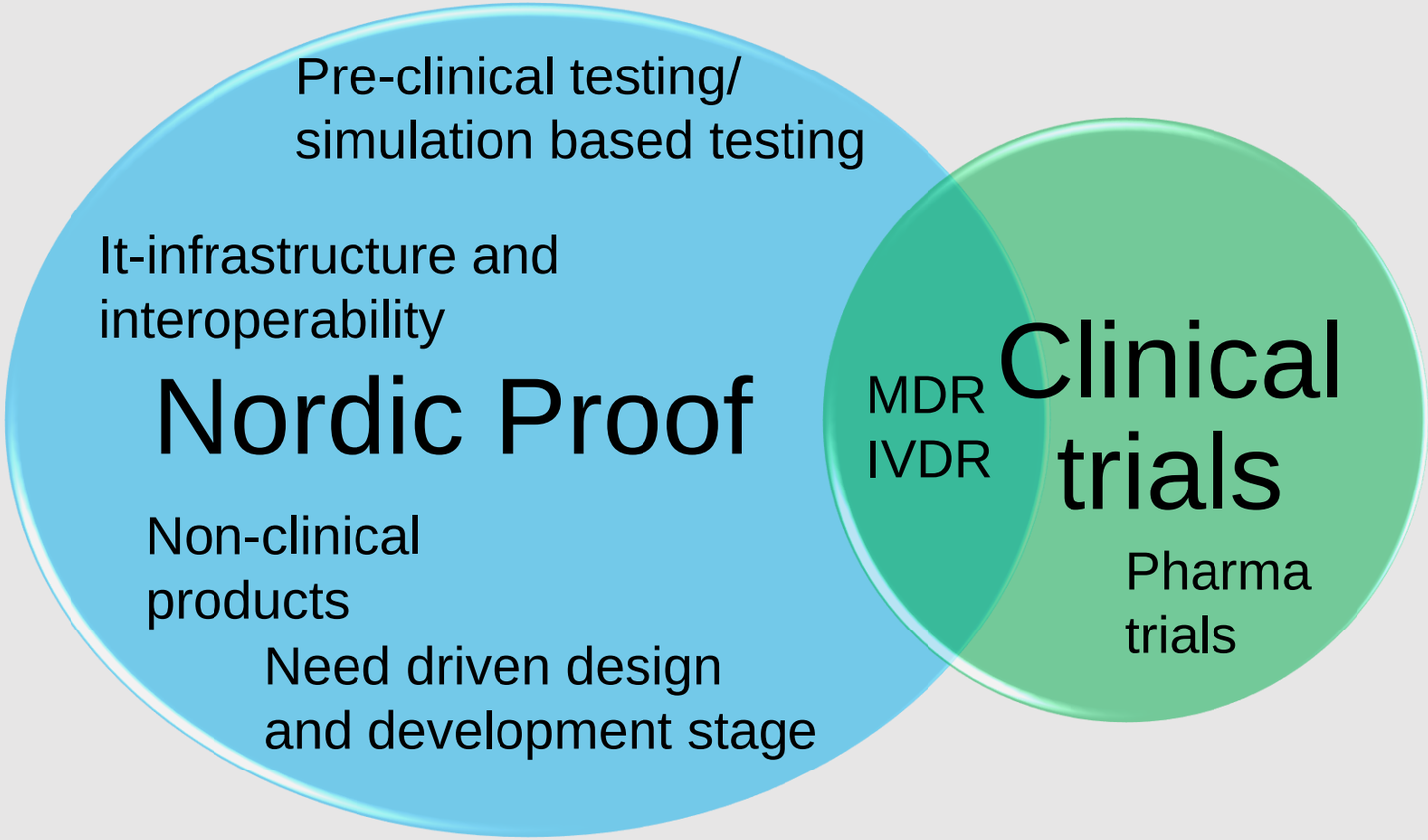
NordicProof

Nordic Proof services

Expert panel workshop	Proof of concept	Clinical and regulatory strategy
Usability testing	Simulation	Contracted research services
Utilization of patient registry data in product development	Technical testing, safety and security	Integration and interoperability
Efficacy studies	Clinical testing and Validation	Cost-Benefit-analysis

NordicProof

Can a future Nordic (clinical) Trial support infrastructure network cover all the different testes and trials?



NordicProof

Established networks for Nordic collaboration, a brief overview of objectives, successes and bottlenecks

NordicPedMed

Sigrun Hjelle

NordicPedMed

NORDIC investigators network for PEDiatric MEDicines

Nordic meeting, 24.April 2025, Gardermoen

Sigrun M. Hjelle
Coordinator NorPedMed and NorTrials
European Correspondent for Norway at ECRIN
NorCRIN Secretariar
Helse Bergen HF

NORDICPEDMED
Nordic investigators network for Pediatric Medicines

Nordic investigators network for Pediatric Medicines

Backgrund

REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

- To improve the health of children in the EU by increasing the availability of safe, effective, and appropriately tested medicines for paediatric use
- **Reduce the off-label use of adult medicines in children**

NORDICPEDMED

Nordic investigators network for Pediatric Medicines

Nordic investigators network for Pediatric Medicines

- Incentivize pharmaceutical companies to develop and test medicined specifically for children
- Require a Paediatric Investigation Plan (PIP) for new medicines, ensuring studies are done in children when appropriate

More clinical trials for children

NORDICPEDMED

Nordic investigators network for Pediatric Medicines

Nordic investigators network for Pediatric Medicines

NORDICPEDMED

Nordic investigators network for Pediatric Medicines

Nordic investigators network for Pediatric Medicines

Background - 1. Article – 2013

ACTA PÆDIATRICA
NURTURING THE CHILD

Acta Pædiatrica ISSN 0803-5253

REVIEW ARTICLE

Limited impact of EU Paediatric Regulation on Finnish clinical trials highlights need for Nordic collaboration

Matti Korppi (matti.korppi@uta.fi)[1], Pirkko Lepola[2], Kim Vettenranta[3], Seppo Pakkala[4], Kalle Hoppu[3,5,6]

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6.Poison Information Centre, Helsinki University Central Hospital, Helsinki, Finland

Keywords
Clinical trial, EU regulation, Paediatric medicines, Research network

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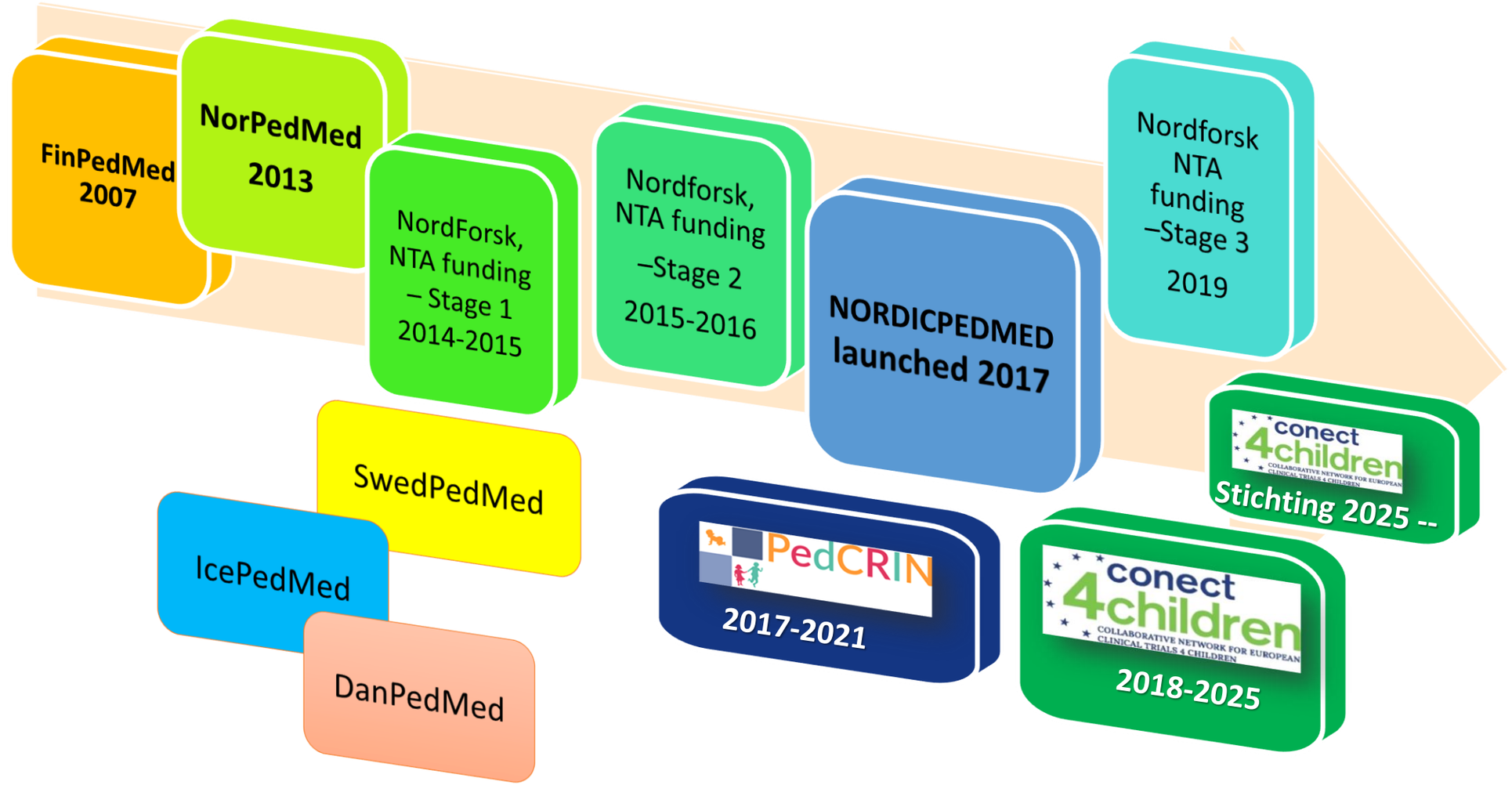
23 April 2013; revised 25 June 2013; accepted 24 July 2013.

DOI:10.1111/apa.12372

ABSTRACT

The Finnish Investigators Network for Paediatric Medicines (FINPEDMED) was established in 2007, to meet the expected increase in paediatric clinical trials following the new EU Paediatric Regulation. Between 2007 and 2012, FINPEDMED received 91 trial requests, 18 trials were started, and in 24 cases, Finnish investigators were not selected by sponsors.

Conclusion: This experience from Finland highlights the need for Nordic collaboration to increase expertise, recruitment base and attractiveness for sponsors.



NORDICPEDMED

Nordic investigators network for Pediatric Medicines

Nordic investigators network for Pediatric Medicines

Launch - NORDICPEDMED 26.1.2017, Oslo

NORDICPEDMED

Nordic investigators network for Pediatric Medicines

Nordic investigators network for Pediatric Medicines

Background – Aim

Pediatric population in Nordic area 5,3 mil.

conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

EnprEMA
European Network of Paediatric Research at the European Medicines Agency

PedCRIN

NORDICPEDMED

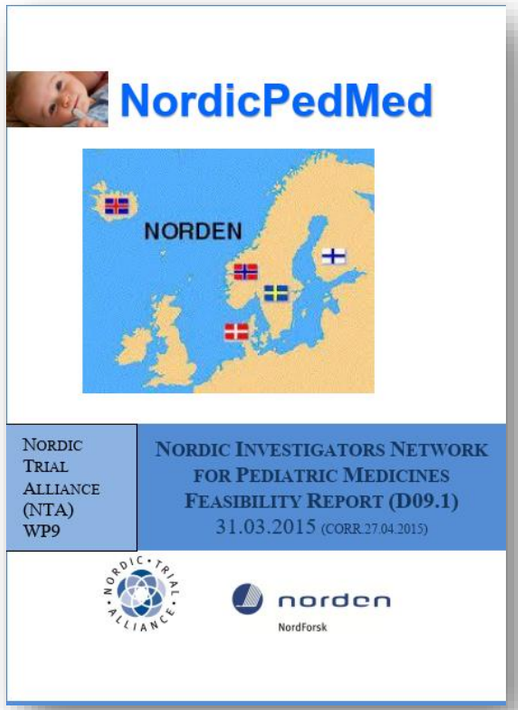
Nordic investigators network for Pediatric Medicines

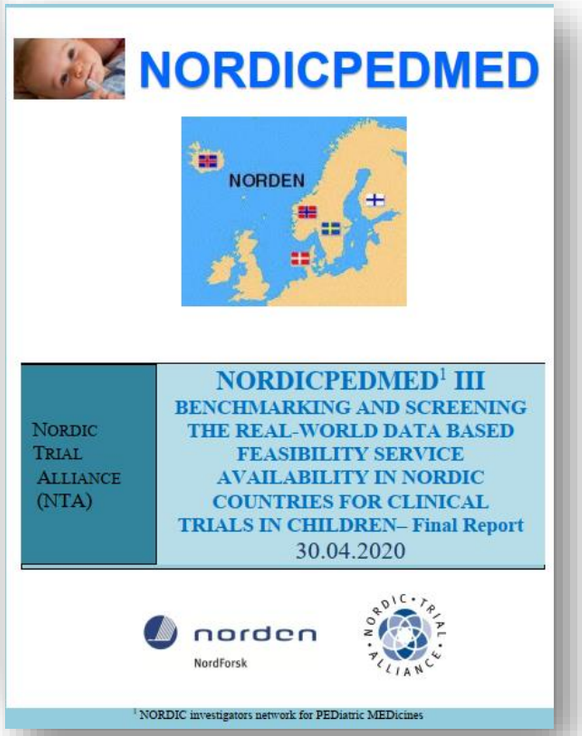
Nordic investigators network for Pediatric Medicines

Goals

- To develop a common Nordic infrastructure for paediatric clinical trials
- To establish a common registry over sites and researchers
- To promote collaboration on a Nordic and European level
- To improve the access to new and existing medicines for children through high quality and ethically sound research

2014-2019 - 3 Project reports to NTA





2.2 Participation and project presentations in meetings

3. Result of Feasibility assessment (Project objective 1)

3.1 Draft concept for a "NordicPedMed"

4.2. Proposal of EPCTRI network to ESFRI Roadmap 2016

4.3 PedCRIN (The Paediatric Clinical Research Infrastructure Network)

6. Developing new innovative research to increase competitiveness

3.2 C4C-Conect4Children - 2018-2024

3.3 PedCRIN – 2017-2020

4. RWD use as a current priority area and prospects in Europe

läkemedel

sto

NORDICPEDMED
Nordic investigators network for Pediatric Medicines

Nordic investigators network for Pediatric Medicines

Status - 2. Article – 2019

ACTA PÆDIATRICA
NURTURING THE CHILD

Acta Pædiatrica ISSN 0803-5253

ACTA PAEDIATRICA PERSPECTIVES

Tardy development of safe medicines for children: a Nordic network offers new platform to reduce this inequity

Estelle Naumburg (estelle.naumburg@umu.se)[1,2], Anders Rane[2], Thomas Halvorsen[3,4], Heidi Glosli[5], Tine Brink Henriksen[6], Àsgeir Haraldsson[7], Jaana Kallio[8], Pirkko Lepola[8]

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DOI:10.1111/apa.14775

NORDICPEDMED Nordic Investigators network for Pediatric Medicines INVESTIGATORS REGISTRY

Main About us Pharma & Biotech Industry Investigators Service Request Contact us

6th Nordic Conference on Pediatric Medicines 2025

The ultimate aimof NordicPedMed is to develop a Nordic network of investigators, centres and national networks with recognized expertise in performing clinical studies on children and increase cooperation both on a Nordic and European level. NordicPedMed have received funding from the Nordic Council of Ministers and NordForsk, through NordicTrial Alliance (NTA) project.

EASTER TIME NOTICE: Service Requests are not processed between the dates 17April and 25April, 2025.

The NORDICPEDMED is a joint paediatric clinical research network within all Nordic countries; Denmark, Finland, Iceland, Norway, and Sweden. The network was established between the years 2014 and 2017. The development of a joint Nordic Investigators Registry was finalized during the years 2018-2019.

The network's objectives are to help meet the therapeutic needs of children by facilitating development, increasing knowledge and

SERVICE REQUEST

1 CDA — 2 Request type — 3 Request summary (R) — 4 Sender contact information and submission

Instructions

- **One Service Request may include only one category at the time (i.e. one trial or one consultation).**
- All Services are provided FINPEDMED/NORDICPEDMED Office hours.
- Basic Service Request is free of charge for all Requesters.
- Consultations are based on annually confirmed fees. See: Service Fees.
- See more: Terms of FINPEDMED/NORDICPEDMED Services.

☐ I have READ and AGREED with the terms of FINPEDMED / NORDICPEDMED Services

Need for Confidentiality Agreement prior to generating a Service Request?

YES NO, PR

2. Medical condition or disease: * **

3. Name of the study or abbreviation of the trial / protocol: *

4. Name of the trial drug(-s) / IMP, and placebo and/or comparator: *

4.1. Trial drug /IMP by ATC code up to the 3rd or 4th level (chemical / pharmacological / therapeutic subgroups) if the 5th level (chemical substance) has to remain blinded: *

5. Pharmaceutical form: *

6. Route of administration: *

7. Trial phase: * **

- ☐ I / II
- ☐ II
- ☐ III
- ☐ IV
- ☐ N/A

SERVICE REQUEST

✓ CDA — ✓ Request type — 3 Request summary (R) — 4 Sender contact information and submission

Which countries do you want to target: * **

- ☐ Finland
- ☐ Sweden
- ☐ Norway
- ☐ Denmark
- ☐ Iceland

1. Pediatric therapeutic area OR specialty / subspecialty (-ies): * **

- ☐ Adolescent Psychiatry
- ☐ Allergology
- ☐ Anaesthesiology-Intensive Care
- ☐ Cardiovascular diseases
- ☐ Child Psychiatry
- ☐ Clinical Pharmacology
- ☐ Dermatology
- ☐ Diagnostics
- ☐ Endocrinology

www.nordicpedmed.com

NORDICPEDMED
Nordic investigators network for Pediatric Medicines

Nordic investigators network for Pediatric Medicines

Results

- Establishment of a common Nordic researcher's registry
- Development of a digital platform for enquiries, enabling coordination of clinical studies across the Nordic region
- Organisation of yearly meetings such as the Nordic Conference on Paediatric and Orphan medicines
- Strengthen the Nordic position within paediatric research and improved treatment options for children in the region

NORDICPEDMED
Nordic investigators network for Pediatric Medicines

Nordic investigators network for Pediatric Medicines

Contact details

NordicPedMed Board:
Chair: René Mathiasen **General Secretary**: Pernille Skovby
Vice Chair: Per Kristian Knudsen

National Contacts – National Representatives:

Finland, FinPedMed: Pirkko Lepola, pirkko.lepola@hus.fi
Denmark, DanPedMed: René Mathiasen, rene.mathiasen@regionh.dk and Pernille Skovby pernille.skovby@regionh.dk
Norway, NorPedMed: Thomas Halvorsen, thomas.halvorsen@helse-bergen.no, Per Kristian Knudsen Per Kristian Knudsen UXPEKN@ous-hf.no
and Sigrun M. Hjelle sighje@helse-bergen.no
Sweden, SwedPedMed: Estelle Naumburg, estelle.naumburg@umu.se
Iceland, IcePedMed: Michael Valur Clausen mc@landspitali.is

6th Nordic Conference on Pediatric and Orphan Medicines
Helsinki 3-4 june 2025

Established networks for Nordic collaboration, a brief overview of objectives, successes and bottlenecks

Nordic Research Preparedness Initiative (NRPI)

Bjørn Gunnar Iversen

Nordic Research Preparedness Initiative – NRPI

Bjørn G. Iversen

25 April 2025

NIPH
Norwegian Institute of Public Health

NRPI – a child of the pandemic

- 5 Nordic public health institutes
- Utilise already good collaboration and similar national structures
- We need to be better prepared to scale up quickly for the next emergency

Sweden	Anders Tegnell
	Magnus Gisslén
Denmark	Tyra Grove Krause
	Pikka Jokelainen
Iceland	Tryggvi Oddsson
	Guðrún Aspelund
Norway	Bjørn Iversen
	Monica Falk
Finland	Hanna Tolonen?
	Otto Helve?

NIPH

Aims and objectives

The overall aim

- Strengthen research preparedness by creating a common framework and networks that can facilitate rapid generation of high-quality knowledge for critical public health decisions by joint efforts of the Nordic countries.

Specific objectives

- Create a common Nordic research framework for preparedness
- Identify barriers for the collaboration, including barriers for data sharing
- Propose possible solutions on how to mitigate or overcome these barriers
- Create “ever-warm” Nordic research networks, ready to respond quickly in case of public health crisis by developing projects for these networks to engage outside of crisis, based on identified critical knowledge gaps and research needs

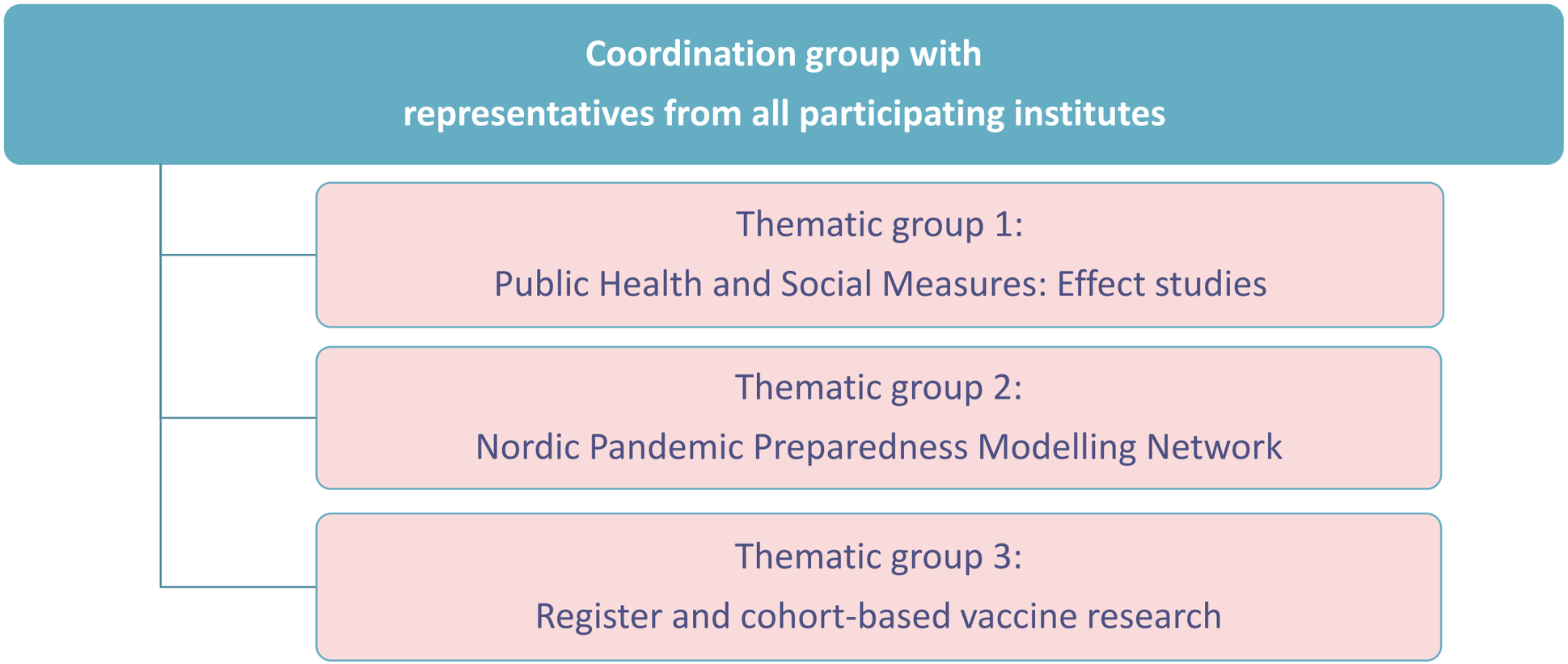
NIPH

Activities proposed

- **Establish an organisational structure**
  Agreement on how the NRPI will be organised and function, including lines of communication.
- **Map and describe**
  - Ongoing and planned research collaborations taking place between Nordic countries and the processes taking place at EU-level.
  - Opportunities and needs within a Nordic collaboration.
  - Some of the main barriers identified so far (legal, organizational, technical, resource-related, definitional, etc.).
- **Case-studies/drills/exercises**
  All stages of a collaborative process can be tested within specific research field (e.g., on vaccine effectiveness or adverse events, modelling, or others) by an exercise, drill, or fictive cases, to exemplify and identify challenges. This will enable a GAP-analysis regarding e.g., databases, opportunities to merge, as well as legal barriers etc.
- **Review process**
  Organised workshops will allow review of findings and to define the way forward with regard to research readiness.
- **Keeping the networks “ever-warm”**
  Identify less resource-intensive pilot projects in areas with common needs. Studies outside of crises will require normal procedures with approvals that can take time but will keep the collaboration warm and facilitate scaling up if necessary. Topics can e.g., be: Vaccine efficacy and side effects, public health and social measures or health inequalities.

NIPH

Thematic groups



NIPH

BE READY

European Partnership for Pandemic Preparedness

Vision of the future European Pandemic Preparedness Partnership

09/04/2025

Funded by the European Union

Pillar 0 (ANRS MIE)
Management

WP 1 (ANRS MIE)
Coordination & Management

WP 2 (ANRS MIE + DLR)
Prepare the Annual Work Plan

WP 3 (ISCIII)
Monitoring & Evaluation

Pillar 1 (ANRS MIE)
SRIA research alignment

WP 4 (ANRS MIE)
Alignment of research priorities

WP 5 (ISCIII)
Synergies & Awareness

WP 6 (ANRS MIE)
Sustainability & exit strategy

Pillar 2 (DLR)
Joint transnational calls (JTC)

WP 7 (DLR + ANRS MIE)
Topic selection, preparation & management of JTCs

WP 8 (DLR)
Evaluation process and proposal selection

WP 9 (DLR)
Follow-up and monitoring of funded projects and funding activities

Pillar 3 (NIPH & ERINHA)
Research ecosystem readiness

WP 10 (ERINHA)
An ever-warm RI ecosystem for basic and preclinical research for pandemic preparedness and response

WP 11 (NIPH + ANRS MIE)
Public Health Research networks

WP 12 (ANRS MIE + NIPH)
EU-wide networks of ever-warm clinical research sites

Pillar 4 (AGES & HPI)
Transversal activities

WP 13 (AGES)
Capacity-building activities & knowledge-sharing

WP 14 (HPI)
Dissemination and Communication

WP 15 (ECRIN)
Ethics and Regulatory issues

WP 16 (VLO EWI)
Accelerating translation of Research into Innovation and Policies

WP 17 (Sciensano)
Enabling a health data ecosystem

WP 18 (AGES + HPI)
Integration of Social Sciences, Global Health, One Health, & Planetary Health

PARTNERSHIP FOR PANDEMIC PREPARDNESS
PILLAR 3

Objective

Strengthen research ecosystem readiness by ensuring that all key components are effectively connected and operational both in inter-epidemic periods and during crises

Activities planned

WP10 – ensure the preparedness and interconnections of **European research infrastructures for basic and preclinical research** for pandemic preparedness and response

WP11 – set up **an ecosystem of public health research institutions and networks** able to provide high-quality knowledge to enable evidence-informed public health decisions in a coordinated manner.

WP12 – further define, establish, further develop, coordinate, and sustain an **Ever-Warm EU wide Network of Networks (EWNN)** of clinical research site networks, able to pivot in case of emergencies.

Funded by
the European Union

Established networks for Nordic collaboration, a brief overview of objectives, successes and bottlenecks

NUHA Agreement
(Nordic University Hospital Alliance)

Åslaug Helland

Established networks for Nordic collaboration, a brief overview of objectives, successes and bottlenecks

NUHA agreement (Nordic University Hospital Alliance) - Catherine Bjerke and Åslaug Helland

- NUHA
- Precision Cancer Medicine
- Real World Data

OSLO UNIVERSITETSSYKEHUS

KAROLINSKA UNIVERSITY HOSPITAL

LANDSPÍTALI

REGION Rigshospitalet

HUS Helsinki University Hospital

Nordic University Hospital Alliance

- Our vision:

Do more for less – together

WHO are we?

NUHA is an alliance between the largest university hospitals in the Nordic region:

- Rigshospitalet, Copenhagen
- Karolinska University Hospital, Stockholm
- Oslo University Hospital, Oslo
- Helsinki University Hospital, Helsinki
- Landspítali University Hospital, Reykjavik

Together, we have EUR 30M citizens

NUHA because…

- Need to accelerate development and solutions that can secure the Nordic welfare model in the future
- We can do this acceleration together because we have a long tradition of excellent data, good healthcare, strong research and innovation as part of our DNA
- We must move knowledge and not people

Four priorities…

- Rare diseases
- Platform trials
- Benchmarking
- Future Health

Goals in the long run…

- One digital Nordic university hospital
- Cross-border data flow (real-time)
- Nordic hub for clinical trials
- Nordic Health Travel Team
- Centres for rare diseases
- Nordic model for platform experiments

Precision Cancer Medicine: IMPRESS-Norway

KLINBEFORSK

KREFTFORENINGEN

RADIUM HOSPITAL FOUNDATION

NordForsk

EU4health

Funded by the European Union

Roche

NOVARTIS

Lilly

AstraZeneca

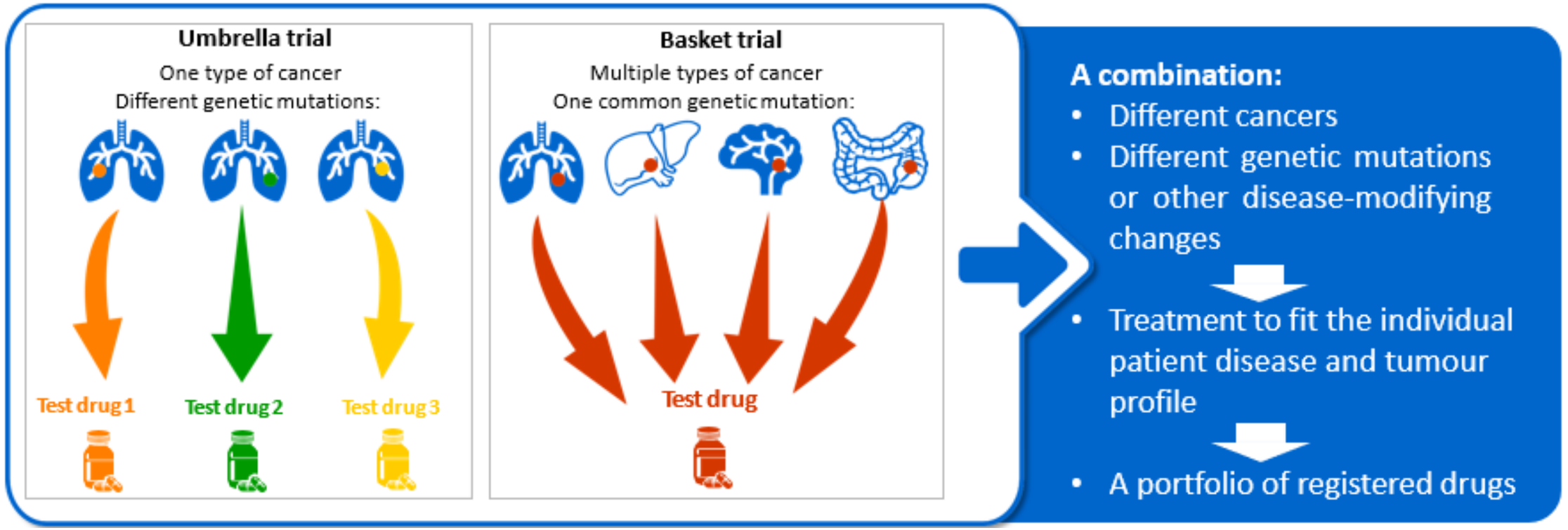
Incyte

MERCK

illumina

GSK

Shared study-design across Nordics – DRUP collaboration based on tumor-agnostic approach



Finprove

FINPROVE - targeted anticancer therapy study

The Finprove study investigating the potential for targeted drug therapy in patients with advanced cancer who no longer have other treatment options. Our Comprehensive Cancer Center coordinates the study which is open at all university hospitals in Finland.

TESTBED SWEDEN
Precision Health Cancer
Innovation hub initiated by Vision Zero Cancer, Genomic Medicine Sweden & SciLifeLab

Updates About

FOCU·SE

FOCUSE is an initiative by Testbed Sweden Precision Health Cancer, founded by Vision Zero Cancer, Genomic Medicine Sweden and SciLifeLab, involving regulators, policymakers, payers, researchers, healthcare providers, patient advocates, and industry to drive the implementation of precision health in cancer care.

Core activity at the Cancer Clinic, Oslo University Hospital

We annually generate vast amounts of patient data stored in a variety of EMR systen

Number of cancer patients:

29 501

Total number of new cancer patients refferred to OUS:

11 172

Cytology:

10 421

Histology:

40 970

Molecular pathology:

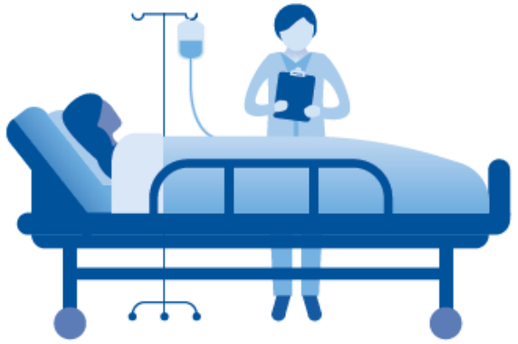
14 734

Radiotherapy: treatment series:

6 960

Radiotherapy: number of fractions:

100 661



Number of beds:

263

Number of over-night stays:

76 182

Number of outpatient consultations:

123 575

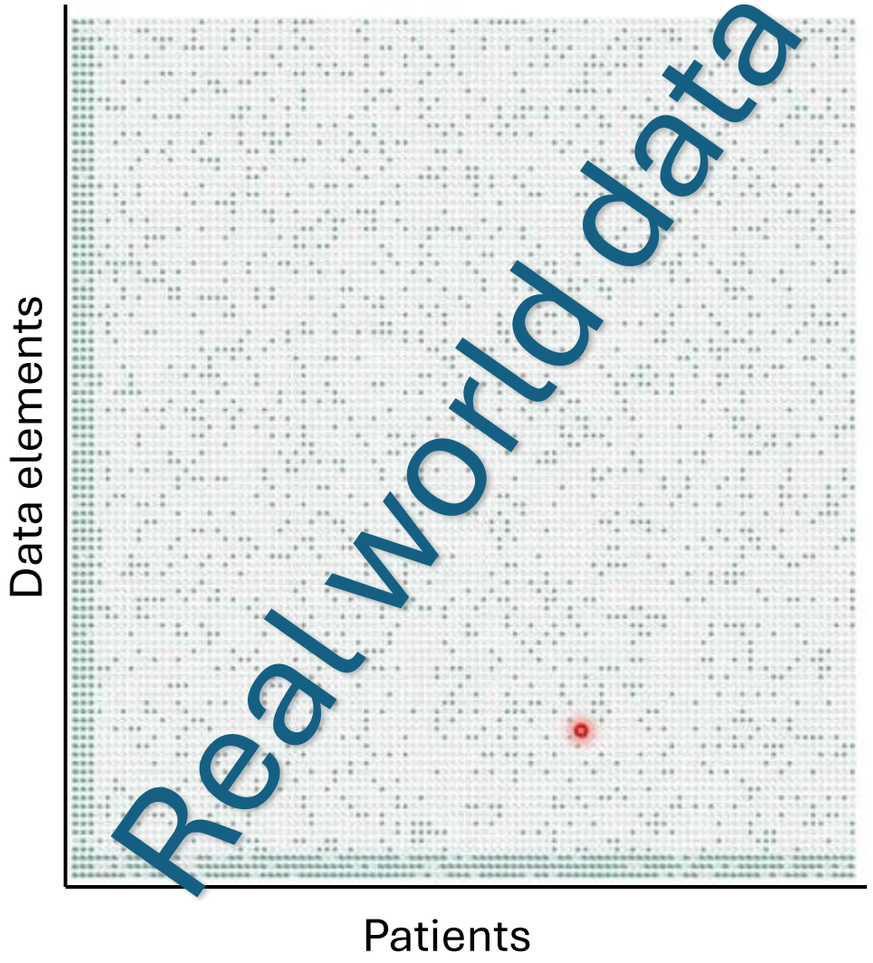
Radiology examinations:

62 129

Radiotherapy: number of patients:

6953

Clinical Trial Data versus Real World Data (RWD)



Clinical Trial

- 10% of patients
- 100% of data elements
- 5% missing data

Quality Registry

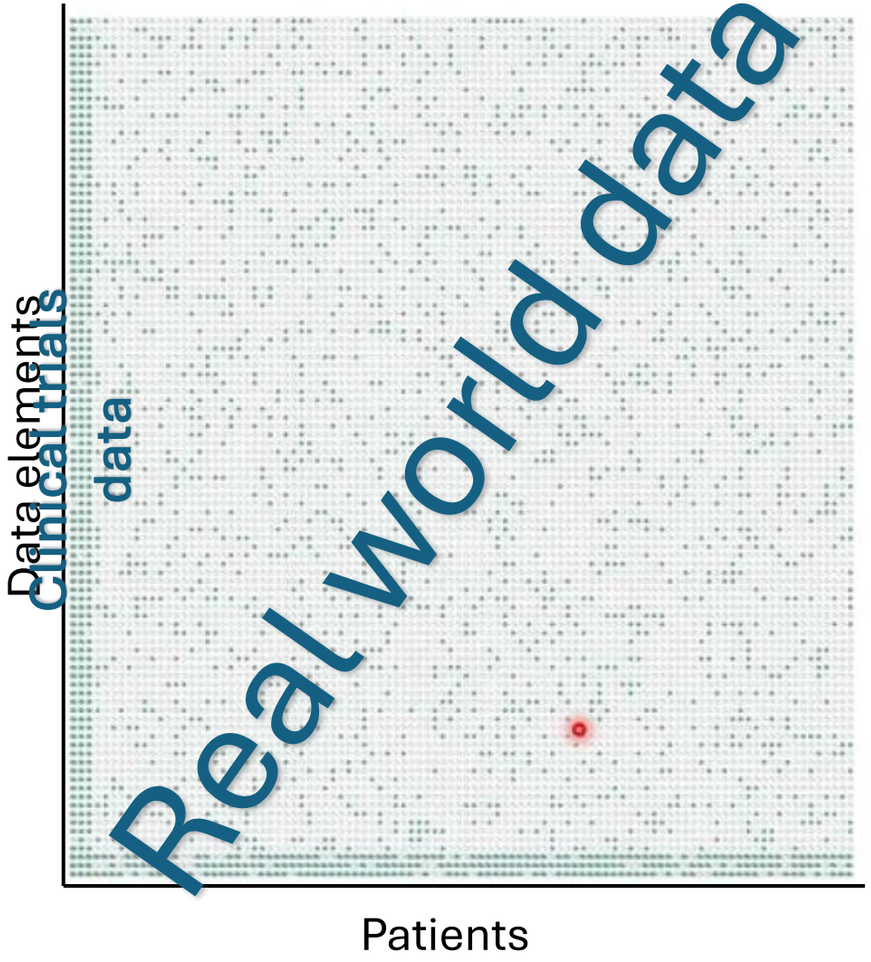
- 100% of patients
- 5% of data elements
- 20% missing data

Clinical Routine

- 100% of patients
- 100% of data elements
- 80% missing data

Real World Data (RWD)

Clinical Trials versus Real World Evidence (RWE)



Clinical Trial

«Perfect data» in an «imperfect population»

- The gold standard in evidence-based medicine with highly internally consistent data

BUT

- Super-human population which does not reflect clinical practice

Real World Evidence

«Imperfect data» in a «perfect population»

- Highly representative of real practice
- Increasingly used in regulatory decision-making

BUT

- Data quality and internal scientific consistency much harder to achieve

Complimentary NOT competitive

Goal:

Learn from every patient to ensure continuous improvement of treatment and care

Approach to RWD and RWE

Current challenges

- Manual plotting for local and national registries and retrospective studies
  - Limited to predefined variables and diagnoses
  - Time consuming, expensive and error prone
- Local solutions and lack of standardization
  - Challenging to compare data across institutions and countries
- Need for transfer of patient level data to central servers for multi centre collaboration
  - Legal, ethical, and IT security challenges

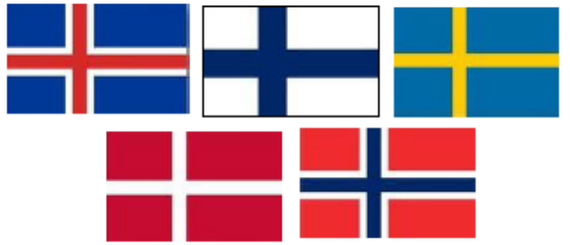
Possible solutions

- **Automated extraction of data from electronic health records**
- **Convert data to standard format and structure**
- **Federated analysis**

The VALO-project - Value from Nordic Health Data

OBJECTIVES OF OVERALL NORDIC PROJECT

1. **Strengthen Nordic cooperation** and the secondary use of health data in research, development and innovation
2. **Jointly prepare for the EHDS legislation** (European Health Data Space) by starting to implement changes and reforms and sharing best practices
3. **Test** in practice and demonstrate the effectiveness of **cross-border Nordic cooperation in the use of health data**
4. to achieve and maintain **Nordic leadership in the secondary use of health data**



the VALO-pilot

Link to more information: https://www.sitra.fi/en/projects/value-from-nordic-health-data-valo/#what-is-it-about

Funded by the Nordic Council of Ministers

VALO Pilot project: Benchmarking care quality for patients with metastatic NSCLC in the Nordic countries

The purpose

This study aims to explore the **treatment patterns** and **patient characteristics** of patients diagnosed with **mNSCLC,** with a focus **on efficacy in different age-groups.**

A separate aim of this study is to pilot the **use of OMOP CDM across the 5 Nordic countries** and to pool data to increase the Nordic RW study impact.

Established networks for Nordic collaboration, a brief overview of objectives, successes and bottlenecks

Nordic Monitoring Network (NORM)

Åsa Michelgård Palmquist

Åsa Michelgård Palmquist
Senior CRA, Uppsala Clinical Research Center (UCR)

UCR

Monitoring – a regulatory requirement

When performing a clinical trial or study, a multitude of regulations and guidelines are followed: CTR (EU Clinical Trial Regulation **536/2014**), MDR (EU Medical Device Regulation 2017/745), as well Declaration of Helsinki and ICH E6 – Good Clinical Practice (GCP), and more.

ICH GCP R3: *3.11.3* ***Quality Control***
Quality control should be applied using a risk-based approach to each stage of the data handling to ensure that data are reliable and have been processed correctly. ***Within clinical trials, monitoring and data management processes are the main quality control activities.***

CTR: *Article 48* ***Monitoring***
In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the clinical trial is in compliance with the requirements of this Regulation, the ***sponsor shall adequately monitor*** *the conduct of a clinical trial.*

NORM
Nordic Monitoring Network

UCRO

NORM – Nordic Monitoring Network

NORM, which is a Nordic network for monitoring of academic studies, was initiated 2011.

https://gcp-enhed.dk/samarbejde-med-gcp-enhederne/norm/nordic-monitoring-network/

Since the start, this network has had yearly meetings and workshops (except during the years of the pandemic) with the focus of sharing experiences regarding the interpretation of Good Clinical Practice (GCP) in clinical trials and how to spread and share the knowledge about GCP to academic investigators and sponsors.

NORM
Nordic Monitoring Network

UCRO

NORM – Nordic Monitoring Network

1st meeting: Bergen, May 2012, during NRC-conference
2nd meeting: Copenhagen, October 2012

3rd meeting: May 2013, during NRI-conference
4th meeting/workshop: Malmö, October 2013

5th meeting: May 2014, during NRI-conference
6th meeting: Oslo, October 2014

7th meeting: Bergen, May 2015, during NRI-conference
8th meeting: Copenhagen, October 2015

9th meeting: Helsinki, October 2016

10th meeting: Copenhagen, September 2018

11th meeting: Oslo, September 2019

12th meeting: Copenhagen, September 2023

13th meeting: Uppsala, October 2024

NRI NETWORKS

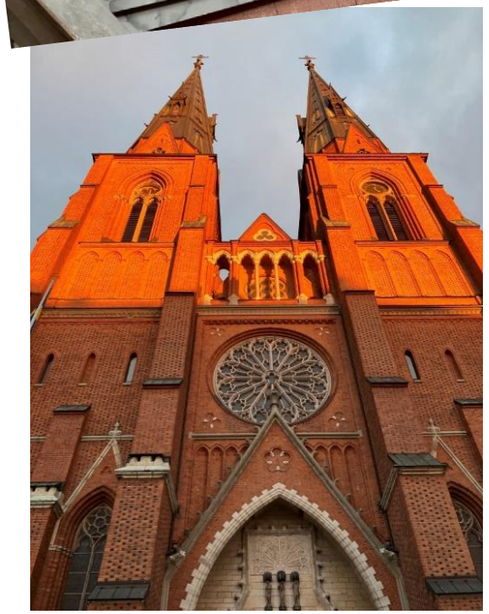
NORM Nordic Monitoring Network

UCRO

NORM 2024

13th Nordic Monitoring Network Meeting

25th of October 2024 in Uppsala, Sweden



New meeting record with
87 registered participants!

Denmark: 24
Finland: 3
Iceland: 2
Norway: 27
Sweden: 31

Program 2024:

- Central monitoring – what is it and how can it be done?
- CEA: Clinical Event Adjudication
- Sponsor Oversight, including Serious Breach
- eTMF
- Guideline revision: Declaration on Helsinki
- CTIS – viewer role used by monitor
- CTIS – documents in Trial Master File (TMF)
- Sponsor GCP responsibility in academic studies

NORM
Nordic Monitoring Network

UCRO

NORM board members 2024

Back row, left to right:

Finland: Leena Partanen, Clinical Research Institute HUS, Helsinki University Hospital, Helsinki

Iceland: Halla Sigrún Arnardóttir, Clinical Research Center, Landspítali University Hospital, Reykjavik

Sweden: Åsa Michelgård Palmquist, UCR (Uppsala Clinical Research Center), Uppsala

Denmark: Birgitte Vilsbøll Hansen, GCP-Unit, Copenhagen

In front, photographer:

Norway: Tanja Igland, Haukeland University Hospital, Bergen

NORM board members 2025

Finland: Susanna Helkkula, The Wellbeing Services County of Southwest Finland, Turku

Iceland: Halla Sigrún Arnardóttir, Clinical Research Center, Landspítali University Hospital, Reykjavik

Sweden: Åsa Michelgård Palmquist, UCR (Uppsala Clinical Research Center), Uppsala

Denmark: Birgitte Vilsbøll Hansen, GCP-Unit, Copenhagen

Norway: Tanja Igland, Haukeland University Hospital, Bergen

NORM
Nordic Monitoring Network

UCR

NORM – why is this network so important?

What do we gain from having this network and meetings?

- It is a **unique possibility** to learn how our Nordic colleagues work that helps us in ongoing, upcoming, and future collaborations in clinical trials and studies.
- **It enriches our day-to-day operations**, and the information is passed on and incorporated in the different countries.
- **Harmonises our way of working**, which improves how clinical trials are conducted, producing reliable and robust results that can be implemented around the world.
- The face-to-face meetings have proven very helpful and **promotes contacts** when you have questions about real life situations in ongoing projects, and **facilitates working together** and improves collaborations and sharing information.
- The meetings have helped to **empower** for instance monitors in Finland, who are only very few and therefore somewhat isolated.

NORM
Nordic Monitoring Network

UCRO

NORM – effects at UCR and in Sweden

What does this network do for UCR and in Sweden?

As a board member, I share information and experiences through:

- Monitoring meetings, internal and in Swedish networks.
- Teaching – internal and external courses (Monitoring course, Uppsala University level course in Clinical Drug Development, as well as other university teaching or for networks like Clinical Studies Sweden / Kliniska Studier Sverige).
- Mentoring new colleagues.
- Improve the UCR SOPs.
- Improvement of UCR's templates.
- Increased understanding for trials in our neighbouring countries .
- Better collaborations.
- Improves the monitoring process, which is the quality control of clinical trials and studies.

NORM
Nordic Monitoring Network

UCR

Nordic contact interface with international/global networks (WHO, CRIGH, ECRIN)

Øyvind Melien

Nordic contact interface with international/global networks

Nordic Cooperation on Clinical Trials Infrastructure Network

April 25th 2025

Øyvind Melien

Representative from Norway in Assembly of Members, ECRIN

Oslo University Hospital

Nordic cooperation – a potential role in a broader international context

Strenghtening of a Nordic cooperation in clinical trials may become a driving force in Europe and as well in a broader international context

Interfaces with international/global networks such as:

European Clinical Research Infrastructure Network (ECRIN)

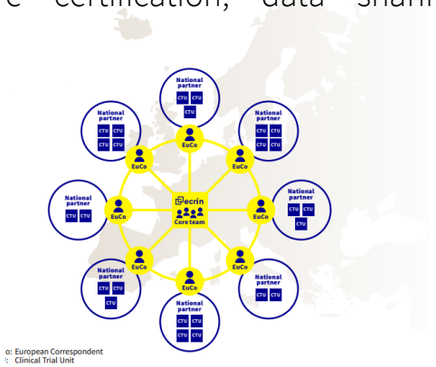
Clinical Research Network for Global Health (CRIGH)

World Health Organisation (WHO) – WHA resolution follow-up

ECRIN, a distributed infrastructure supporting multinational clinical research in Europe

1 - Support **multinational trials** in Europe (investigator-initiated and SME-sponsored trials) through **operational services to trial management** tasks: regulatory, ethics, monitoring, vigilance, data management, data sharing. Acts as service provider to study sponsor, through disease-agnostic services.

2 - Develop **tools, methods and partnerships** for multinational trials (ethical/regulatory database, data centre certification, data sharing tools, personalised medicine, platform trials)



CZECRIN
FCRIN
HNHRA
KKS Netzwerk
ItaCRIN
NCTO
PtCRIN
SLOVACRIN
NorCRIN
SCReN
Spanish Clinical Research Network
swiss clinical trial organisation
POLCRIN
GRECRIN

13 Members & Observer Countries

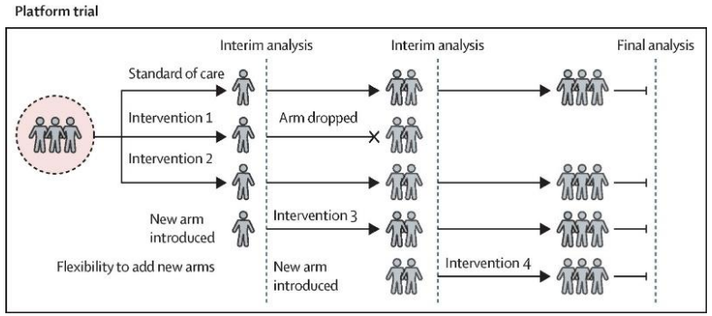
130 CTUs in our network

361 Million citizens represented

79 Trials in ECRIN portfolio

Long-term perspectives for ECRIN

- Develop operational support to platform trials
  - building on the CoVID experience
  - and on new pandemic preparedness trials
  - to promote platform trials in other medical fields



- Further develop data sharing instruments for clinical trial data in Europe

- Promote synergies and cooperation with other medical research infrastructures (BBMRI, EATRIS, EuroBioImaging, Elixir)

- Develop partnership with pan-European investigation networks (rare diseases, pediatrics, infectious diseases etc)

- Expand ECRIN Membership to other Scandinavian countries

Clinical Research Initiative for Global Health (CRIGH)

Preamble: OECD GSF project – preparations for CRIGH

First General Assembly Tokyo 2018

Second General Assembly Paris 2019

Third - fifth General Assemblies Virtual 2020, 2021, 2022

2023:PARIS!


nature.com > nature > correspondence > article

MENU nature

Correspondence

Global health: Boost multinational clinical research

Jacques Demotes Mainard

Global cooperation in clinical research maximizes access to patients, enables resource sharing and increases the applicability of research findings. Yet academic trials are rarely multinational because they are beset with funding problems and variations in legal, regulatory and ethical requirements. The Clinical Research Initiative for Global Health (CRIGH) has taken up the challenge to overcome these.

CRIGH is a worldwide partnership of research institutions and organizations that aims to establish a framework for international cooperation in non-commercial clinical trials and to promote evidence-based medicine (see www.crigh.org). It is a follow-up to the Organisation for Economic Co-operation and Development (OECD)

CRIGH

Clinical Research Initiative for Global Health

Implementation project following OECD Recommendation

40 member/observer organisations from all continents, including OECD and WHO

Secretariat: ECRIN & NIH, involvement of Japan in progress

Current activities centered on 6 projects

P1: Infrastructure and funding Lead: ECRIN.

P2: Global core competencies Lead: F-CRIN, France

P3: Research ethics Lead: National Cancer Center, Japan.

P4: Patient involvement Lead: National Institutes of Health (NIH), USA.

P5: Comparative effectiveness research/Health Technology Assessments Lead: KCE, Belgium, NIPH, Norway.

P6: Multi-national data management and sharing Lead: ECRIN, Harvard

CRIGH

Impact of the WHA 75.8 Resolution

World Health Organization

SEVENTY-FIFTH WORLD HEALTH ASSEMBLY **WHA75.8**
Agenda item 16.2 **27 May 2022**

Strengthening clinical trials[1] to provide high-quality evidence on health interventions and to improve research quality and coordination

Adopted May 2022

Published September 2024

CRIGH

Major Milestones achieved in last 12 months

GCTF
Global clinical trials forum
WHO Managed Network

2022

WHA resolution 75.8

2023

Global clinical trial forum (GCTF)

Proposed a new vision for clinical trials

2024

Launch of WHO Guidance

Researchers, industry, regulators ethics authorities, funders, patient groups, health authorities

2025

Launch of global action plan for strengthening clinical trials (GAP-CTS)

World Health Organization

Global action plan for clinical trial ecosystem strengthening (GAP-CTS)

WHO initiative with focus on the following action points:

GLOBAL ACTION PLAN FOR CLINICAL TRIAL ECOSYSTEM STRENGTHENING
Action 1: Strengthen local leadership and national support for sustained infrastructure and funding
Action 2: Enhance engagements with patients, communities and the public in trial life cycle
Action 3: Address barriers to clinical trials in under-represented populations
Action 4: Enabling well designed, policy relevant trials, including adoption of innovative designs and digital technologies
Action 5: Accelerate access to fit-for-purpose training packages for clinical trials
Action 6: Improve coordination and streamlining regulatory and ethics review
Action 7: Engage clinical practitioners to integrate clinical trials into health systems and practices
Action 8: Reduce waste, advance transparency
Action 9: Expand mutually beneficial multi-national health research and clinical trial collaboration

Global Clinical Trials Forum
WHO 2nd April 2025

Discussion points:

Clinical Trial Unit (CTU) Maturity Framework

- Need to define model for CTUs

1. What is the scope of the CTU Maturity Framework?

- To increase capacity of CTUs – specifically in LMIC (or countries with less developed clinical trial facilities / underserved underrepresented populations). Some units conduct a lot of research but are unable to take part in multinational clinical trials.
- To define a CTU (this could be separated into commercial and non-commercial), characterize and evaluate a CTU
- Research should be based on scientific excellence and participant safety
- Training should be developed off the back of this document
- Audience: Regional offices, national health agencies, people who run clinical trials
- Inclusivity and adaptability: the framework must address diverse national and institutional contexts and address LMICs while being globally relevant. The framework should allow CTUs to develop within their context, and not all CTUs need to achieve the highest level.

Coordination of CTUs

- Who will take the responsibility?

Risk-based approach in Clinical Research

- Look to previous OECD recommendations

Challenges:

- Lack of funding
- Lack of operational level