

NorCRIN

Norwegian Clinical Research Infrastructure Network

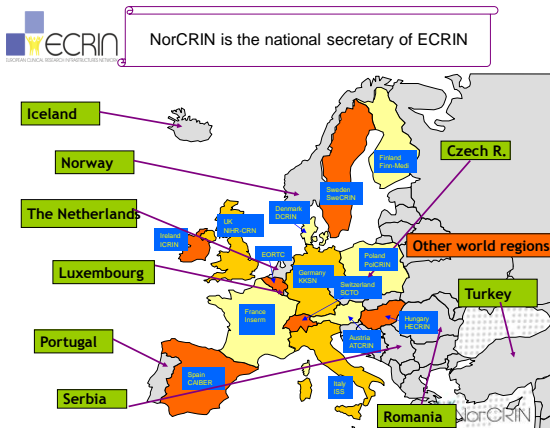


Sigrun Kristine Sæther
NorCRIN Network coordinator
UNIKARD symposium, 27. November 2014



NorCRIN network influence on clinical trials

- Current status
- Some expectations



Competence and expertise at NorCRIN partners



HISTORY

National cooperation project (consortium). Consortium agreement signed in April 2014.

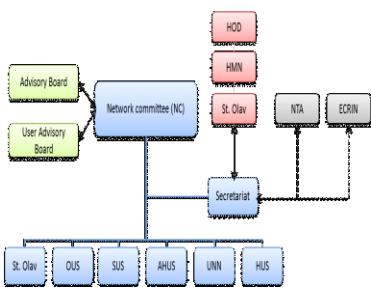
Initiator: The Ministry of Health and Care Services (HOD)

- Responsible for the coordination and operation of the network is placed at StOlav

- NorCRIN secretariat established at StOlav August 2012



Organization of the NorCRIN core team (blue), Advisory boards (green), and communication lines to Norwegian authorities (red) and international infrastructures (gray).



NorCRIN secretariat

- NorCRIN project manager and main responsible for the NorCRIN project
- NorCRIN coordinator is in charge of daily progress and implementation, facilitation and coordination of the work packages, and reports to the Project Manager.
- NorCRIN study coordinator
- Access to one clinical monitor
- ECRIN correspondent is a liaison between ECRIN and NorCRIN and will facilitate contact between clinical researchers in Europe and Norway.
- The national scientific member of the ECRIN network committee represents Norway in the ECRIN network committee.

Contact information: NorCRIN homepage : <http://www.norcrin.no/kontakt/>





NorCRIN main goal

- Strengthen and facilitate cooperation in all clinical research in Norway
- NorCRIN network will be integrated into the European research network for clinical research, ECRIN

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Expectation with establishing NorCRIN



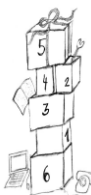
- More national, investigators initiated clinical studies
- More industry financed clinical studies in Norway
- Larger participation in international (Nordic/EU) studies
- Speedier conduction of clinical studies
- Better facilities for research-based clinical practice

NorCRIN

We are developing through defines Work pacages

Work Pacages 2012-2014

- Establish NorCRIN hub
- NorCRIN home page www.norcrin.no
- Establish GCP course template
- National SOPs for clinical drug trials
- Monitoring
- Overview of Norwegian Clinical Research Networks
- Manufacturing of study medication
- Development and implementation of a national webCRF



NorCRIN

THE NORWEGIAN RESEARCH COUNCIL



- 2012 → NorCRIN applied for funding to The Norwegian Research Council.
- We got no money **but** we are in the the **Norwegian Roadmap for Research Infrastructure.**

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- 2014 → New application

NorCRIN

Application 2014

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Work Pacages 2015-2019

- Management and coordination of NorCRIN
- Develop and maintain SOPs
- Monitoring
- **Cooperation with the Industry**
- e-CRF
- **Procedures for non-pharmaceutical interventions**

NorCRIN

Our Services



NorCRIN currently offers consultancy and access to:

- National Procedures for Clinical drug trials (SOPs)
- Monitoring
- ICH GCP-training
- ICH GCP-consultancy
- Data Management («webCRF» and other e-CRF)
- NorCRIN website www.norcrin.no



NorCRIN supported clinical trials Norway



1. **Ipi4-study:**
 - National cancer study: Patient with Melanoma
 - Sponsor: Oslo University Hospital (OUS)
 - PI: Steinar Aamdal, Radiumhospitalet
2. **RituxME:**
 - Chronic fatigue syndrome
 - Sponsor: Haukeland University Hospital (HUS)
 - PI: Olav Mella, HUS
3. **The NOR-SWITCH study:**
 - Efficacy of switching from innovator infliximab to biosimilar infliximab in Rheumatic diseases, Inflammatory bowel diseases, Chronic plaque psoriasis.
 - Sponsor: Diakonhjemmet Hospital, Oslo
 - PI: Tore Kvien, Diakonhjemmet Hospital



NorCRIN contribution



Information and consultancy during preparation

- Planning of the trial
- Information on regulatory and ethical requirements
- Information on sites and participant recruitment
- Information on clinical research centre
- Information on insurance
- Information on cost and fundings and contracts

Service during conduct of the trial

- Support
 - Collect signed contracts and CV
 - Amendments
 - Trial Master file (TMF)
 - Investigators site file (ISF)
 - Collection of essential study documents
- Newsletter
- Monitoring
- Data management
- Etc.



Next 5 years?



Bottle neck

- Agreements
- Process flow, roles, responsibilities and deadlines
- Information flow

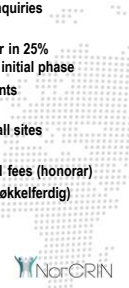
Focus areas

- Effectiveness
- Predictability (forutsigbarhet)
- Quality



Services

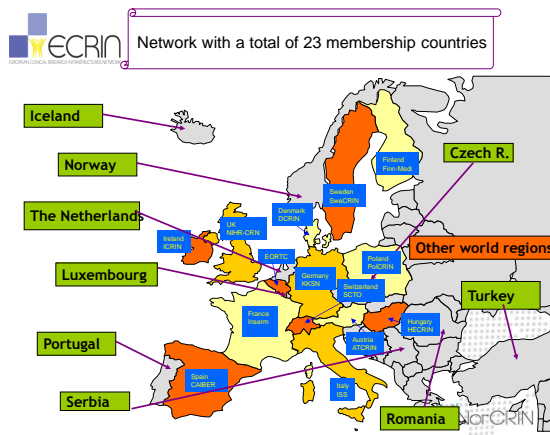
- «One-stop shop» - inquiries (henvendelser)
- A Project coordinator in 25% position pr project – initial phase
- Framework agreements (rammeavtaler)
- One negotiation for all sites (forhandling)
- Reduced/harmonized fees (honorar)
- Turnkey solutions (nøkkeferdig)



In a short term...

Researchers' need

- New services on web site
 - Price on Lab services
 - Price on Pharmacy services
 - Framework agreement on translations



Ongoing International clinical trials

1. Norden via Nordic Trial Alliance
 - PregMet: St.Olavs Hospital is in leadership
2. Europa via ECRIN
 - MENAC**
 - Sponsor PRC/NTNU, Trondheim
 - Participating countries: Norway, Switzerland, The Netherlands, Denmark, Germany and UK
 - EORTC 40091** (multinasjonal randomisert kreft studie)
 - Sponsor EORTC, European Organisation for Research and Treatment of Cancer, Belgia
 - Participating countries: Norway (Haukeland HF), Switzerland, Austria, Germany, Denmark and UK
 - EudraCT version 9 Pilotstudie** (uttesting av ny database)
 - Sponsor: non-commercial actors (16 from different countries)
 - Participating countries: Norway (Haukeland HF), Spain, Denmark, France, Italy, The Netherlands and Portugal



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