PM

Nordiska ministerrådet

Till

Kopia

Från
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Ämne
Mötesanteckningar möte i arbetsgruppen för kliniska studier 16 februari

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Mötesanteckningar arbetsgruppen för kliniska studier

Plats:NMRS, Ved Stranden 18
Datum: 16 februari 2011

Närvarande:

Sverige	Birgitta Stegmayer, Head	Unit of Epidemiology National Board of Health and Welfare Department of Statistics and Evaluation
Finland	Timo Keistinen medicinalråd	Social- och hälsovårdministeriet
Island	Kristián Erlendsson	Landspítali
Danmark	Ole Andersen, Overlæge, dr. med. MHM	Sundhedsplanlægning Sundhedsstyrelsen
Danmark	Fuldmægtig Mia Francis Nielsen,	Indenrigs- og Sundhedsministeriet
Danmark	Kontorchef Niels Würgler Hansen	Indenrigs- og Sundhedsministeriet
Danmark	Specialkonsulent Lene Grejs Petersen	Lægemiddelstyrelsen
Danmark	Sven O. Skouby, Professor, MD, DSc	Director of Endocrinological and Reproductive Unit Dep. Ob/Gyn. Herlev Hospital, Faculty of Health Sciences University of Copenhagen and Department of Thrombosis Research, Esbjerg, University of Southern Denmark
Norge	Ernst Omenaas, Professor	Helse Bergen HF
Norge	Direktör Marit Endersen	Helsedirektoratet
Norge	Avdelningsdirektör Maiken	Helse- og omsorgsdepartementet

	Engelstad	
Norge	Avdelningsdirektör Jan-Petter Akselsen	Statens läkemedelsverk
	Bengt Fellström, Professor	NMR
	Helene Norberg	NMR
	Maria Nilsson, PhD	NordForsk, NMR
	Rune Thele	NordForsk, NMR
	Marcus Zackrisson	NICe, NMR

Welcome and presentation

Presentation of the project (Helene Norberg, see ppt pictures)

Presentation of NordForsk (Maria Nilsson, see ppt pictures)

Presentation of NICe, Marcus Zackrisson

Presentation of background, (Maiken Engelstad, see ppt pictures)

Presentation of summary from interviews and questions to country representatives, (Bengt Fellström, see enclosed document)

Discussion:
The countries agree on the overall picture and challenges. Both better framework and change in attitude is needed. The countries shared the view that time period is importand, data could be used more streamlined, access to public registers is important. Nordic strenghts in biobanks and quality registers should be used. Nordforsk is facilitating a project about Nordic cooperation within biobanks.

Actions are needed for both industry and public, these two interests can be combined and focus should not be to distinguish between them. A pressure to focus more on clinical trials will come with the decision to cooperate at a Nordic level with this question.

The representatives discussed which services that are needed. Clinical trials unit registers, database with contact points for clinical trials, register for established networks, access to and faster recruitment of patients.

What kind of service or organisation would be responsible for facilitating clinical trials? In a long term perspective it is possible to see a one-stop shop, but now a coordination unit with website with contact points could be realistic. May be a pilot project to run a clinical trial coordination in a certain area.

There is a need for secretariat, networking with specialists, statistical assistance, support for application. There are today research centers in some areas (but not all) that could build a ground for the cooperation to avoid new organisations and dublication. Both the Nordic and political connection and strong connection to the medical field is necessary. Existing organisations need to be connected to the Nordic level. A Nordic institution for example Nordforsk, NICe or both in cooperation can work with the national ecrins. A virtual network of ecrins with a secretariat in Nordforsk was discussed.

Website with information is suggested as a first step. The working group need to have big ambitions but work with small step. Every step needs to be evaluated not to get stopped.

Industries will not be involved in the working group at this point. This work will open up for industries but is not designed with specific focus on industries.

The working group agrees to recommend a pilot for three years. Pilot areas were discussed and rare diseases and medicin in children were suggested. These suggestions need to be specified according to clear criteria and expected outcomes.

Bengt Fellström will continue his work and include this discussion in his paper. This will be sent out for comments before the next meeting. The group will get one week to read and then Bengt will revise the report according to the comments.

Money for the secretariat of clinical trials will be checked within the Nordic Council of Ministers.

The report will be written in Swedish.
Next meeting at 10-15 on 17 march.

/Helene Norberg