

Till

Kopia

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Mötesanteckningar

Mötesanteckningar arbetsgruppen för kliniska studier

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Närvarande:

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	Helene Norberg	NMR

	Maria Nilsson, PhD	NordForsk, NMR
	Marcus Zackrisson	NICe, NMR

Presentation of report

Feedback and discussion:

Denmark:

Denmarks main points was that it is important not to build new organisations. The connection to the EU activities could be more focused. The language should be english. Denmark finds 3-5years a rather long time before an evaluation. The report needs more structure and focus.

Norway

Norway find the initiative important. Critical points is the restricted efficiency in infrastructure. To build a network should be visualized. The plan should be more focused. Some elements are doubtful, for example approval in Nordic area and feasibility database.

Sweden

Sweden sees need for coordination but not a coordinating unit. The report should be more focused and more about what has been done on EU level. Sweden needs first to see what should be done on the national level before a nordic network. One problem that ecrin-network does not work.

Finland

Finland finds links to hospitals important, as well as links to Ecrin and EU. The question is how you can get more coordination.

Island

Island asks for a more clear definition, also in the title. The background is decreasing but how many subjects are included is also important. Studies are bigger now. The study needs more information in background. Main aim should not be only to increase number of studies. What is the need could be clearer presented. Iceland strongly urges that this is an important work.

Nos-M

Nos-M points out that clinical studies are increasing. Clinical trials is something else. It is important to have the right perspectives. European perspective is investigator driven clinical trials, which is an important perspetive. From a european perspective clinical studies has moved to another european country. Research councils should be mentioned. The universities are hidden in the report.

Nordforsk

The secretariat should be focused, small scale and should show results. The mandate of the secretariat should be anchored among the countries.

NICe

Points out that it is possible to separate financing and location of secretariat

Bengt

The similarity of nordic countries is a strong factor for coordination. A full database for a feasibility study is not the idea but something to start with. This database should be attractive for researchers and clinical trials units so that they have incentive to update the information themselves.

Maiken

We agree on

- Work with structure and focus of the report
- Clear on definition, multicenter randomized clinical studies
- The relation between national, nordic, eu, should be stressed in the report. Nordic level should support national and EU level. One voice within EU would be good. Push a positive example but not duplicate national or european structures.
- Start small, but lots of opportunities if we succeed.
- Taken point of fast evaluation.
- Make it easy to get information. Today some areas have network.

OECD process has three focuses, harmonization, regulatory process, education and patient involvement.

The group concluded that it may not be wise to speak about coordinating unit. "Nordic network" is better.

The service to start with is an information database.

The purpose with the project is more clinical studies, support the national work, facilitate and support ecrin network.

However, it is a problem that Ecrins differ between countries.

Denmark points out that there should be no new bureaucracy, and that the project needs evaluation after one year on structure and later on trials and processes that takes longer times.

Sweden points out the need to solve the national situation. It also has to be more clear which are the advantages for me as a researcher, as well as for national work.

Finland points out that the Nordic voice in decision making in EU is important. Nordic value needs to be stressed.

Nos-M suggest that this project could be presented as an european pilot

Iceland points out that they support, and that with EU the nordic area gets more important.

It should be more clear in the report that even if information exists, it needs to be more easily available. A website today can do alot.

The tasks for the Coordinating function:

Courses, information strategy, pilot projects

OECD propose courses

One question is if the ecrin are interested in a nordic network?

The way of thinking could be same as biobank network.

Another question is to what extent education is fulfilled at national level?

In Sweden the answer is yes. In Denmark it is incorporated in phd. In

Norway it is lacking. OECD found that there are no obligatory courses in any nordic countries. Denmark argues that they are not sure if they can support a common course.

The working group agrees on to look into a need on education, and if there is a need so arrange it. This could be done in several ways, for example provision on information on education. Nordic countries can collaborate on

courses. OECD recommends that there should be a formal requirement on education.

Ethics committés:

The group discussed coordinated ethic approval as a long term goal. One way is to make them meet. It is an ambition in the EU system that one application approved in one country should be approved in other EU countries.

Getting the ethics committés together and speak what they can do together is one first step.

The working group agreew to work in this area, but not propose to change any laws at this stage.

Feasibility studies:

Feasibility studies is a crucial question. Norway is against and argues that we will never reach a point that we can get information with a patient list.

Pilot project:

The subject is to point what you get out of it, with examples in the report.

Need examples "this could be solved and is needed" for example medication for children, cheap medicin, the issue is to show how important it is to get these results fast.

Bengt will get short descriptions on examples.