Success factors for Nordic clinical trials

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Real estate

- **Location!!!**
- **Location!!!**
- **Location!!!**

Randomised clinical trials

- **Quality!!!**
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- **Quality!!!**

Randomised clinical trials

- **Quality!!! – no systematic error (bias)**
- **Quality!!! – no systematic error (design)**
- **Quality!!! – no random errror (outcomes and analyses)**

1. Ethics

- Map national differences in the interaction with ethics committees

- Develop ‘common best practice’ documents on informed consent and on interaction with the ethics committees

2. Competent authorities

- Map national differences in the interaction with the competent authorities and the regulatory framework for investigational medicinal product, devices and for other types of interventions

- Develop common ‘best practice documents’ on interaction with the competent authorities, on archiving,, and on management of IMP, devices and for other types of interventions

3. Pharmacovigilance

- Map national differences in the adverse event reporting regulations and procedures
- Develop common ‘best practice documents’ for adverse event reporting procedures

4. Data management

- Map existing resources for data management solutions in the public research centres within NTA
- Develop ‘common best practice’ documents on data processing

5. Monitoring of clinical research

- NTA will harmonise with the Nordic monitoring network (NORM).

- A risked-based approach shall be applicable to all types of interventions.

6. Transparency

- Map national and Nordic existing resources for, and, develop ‘best practices’ for registration and publication of trial protocols before inclusion of the first participant

- Map national and Nordic existing resources for, and, develop ‘best practices’ for upload of depersonalised individual patient data

8. Design of studies

- Describe current national/international recommendation for different types of trial design

- Provide recommendations for ‘best practice’ based on current evidence, national and EU regulations and guidelines and the best scientific and ethical research methodology

9 a. Public liaison and personal data protection

- Develop a plan for clinical research communication with society and patient organisations

- Identify any particular needs or obstacles (eg, patients attitude towards research) for effective communication, and suggest solutions to such needs

9 b. Public liaison and personal data protection

- Map national differences in the regulatory framework for processing personal data (including biobanks - collection, circulation and storage of biological samples, taking advantage of the EU biobank infrastructure (BBMRI)

- Develop common ‘best practice documents’ to serve as ground for recommendations for harmonisation

10. Statistical analyses of clinical research

- Describe current national/international recommendation for statistical analysis in trial design and trial reporting

- Provide recommendations for ‘best practice’ based on current statistical evidence, national and EU regulations and guidelines and the best scientific and ethical research methodology

11. Education and career structure

- Map existing resources for national and Nordic education and training of sponsors, investigators and other research personnel

- Make recommendations for Nordic training programs and provide suggestions for future career structure for personnel working with clinical research

12. Investment in clinical research

- Develop a sustainable proposal for Nordic investment in clinical research

- Increase motivation for physicians and other health care personnel to do clinical research

14. Advantages of the Nordics and the marketing thereof

- Map national and Nordic strong clinical research communities, populations, and other specificities in the Nordics

- Updated and clear home page (web site)

15. Study logistics

- Identify any particular needs or obstacles in early study logistics (e.g., participant recruitment, administrative burden (investigator CV), financing and time for investigators to do research)

- Develop recommendations or solutions based on knowledge transfer with industry

16. Insurance in the Nordics

- Map national differences in the regulatory framework for insurance policies for (participants, trialists, protocol, etc.)

- Develop common ‘best practice documents’ to serve as ground for recommendations for harmonisation

17. Investigational medicinal product logistics

- Map national differences in the regulatory framework for circulating investigational medicinal product (IMP) logistics

- Develop common ‘best practice documents’ to serve as ground for recommendations for harmonisation

7. Collaboration between industry and academic investigators 1/2

- Map national initiatives and existing recourses for facilitating collaboration between industry and academic investigators regarding clinical research

- Provide recommendations for best future practices regarding collaboration

7. Collaboration between industry and academic investigators 2/2

- Develop a proposal for knowledge transfer - learn from industry as to ‘how’ to get the research done in time (logistics, administration, feasibility), share best practices, lessons learned, and failures