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Patient centric, decentralised clinical trials – a national project

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Decentralised interventional clinical trials

- During 2020-2021, the Swedish Medical Products Agency carried out a feasibility study and a subsequent project about patient centric, decentralised clinical trials
- The project aim was to establish conditions for how interventional clinical trials can be carried out decentralised in Sweden
- The work was partly financed by the Swedish Innovation Authority

Decentralised investigational clinical trial

- A decentralised interventional clinical trial can be described as a method for, remotely and/or with the help of digital tools, collecting data within the framework of the trial. It can be consent data, randomisation, and inclusion but also safety and efficacy data for the investigational medicinal product in the trial
- Trials that contain both decentralised and traditional elements are often referred to as hybrid trials

The project - why and how

- Increased knowledge and predictability about the conditions for conducting this type of clinical trials in Sweden
- More patients should be offered the opportunity to be included in a clinical trial regardless of where they live
- Increased number of clinical trials
- Regulations, guidelines and established practice were analysed, internally and in work shops nationally and within EU
- Provided several advice meetings, free of charge, regarding decentralised elements in investigational clinical trials
- Invited sponsors to participate with CTA as pilots

The Pilots

- Five interventional clinical trials with decentralised elements were followed in the project
- The decentralised elements in one or more of these trials include:
  - remote electronic consent
  - home sampling administered by the patient himself
  - remote visits within the framework of the trial
  - medical device solution to capture symptoms of possible side effects
  - distribution of investigational medicinal products
  - medical device solution to register compliance to treatment

The project deliverables

- MPA website dedicated to DCT with continuously updated Q&A in support of DCTs
  - Sponsors and investigators of the pilot studies have been interviewed for best practice – summaries at the website
- As regulators confident and knowledgeable with the DCT approach
- Increased number of applications of DCTs

Swedish Medical Product Agency - General considerations on DCT (1/2)

- Planning for decentralised steps in a clinical trial requires a careful and study-specific risk-benefit assessment
- The reasons for performing decentralised elements must be based on a scientific basis and may, for example, be;
  - an increased opportunity to include a relevant study population
  - collection of additional relevant data
  - reduced risk or burden for patients
- Cost efficiency is not an acceptable reason to introduce decentralised elements

Swedish Medical Product Agency - General considerations on DCT (2/2)

- The same requirements regarding ICH GCP, GMP, the scientific value of the study and the safety of subjects, apply to decentralised trials as to traditional trials
- The investigator's overall responsibility in the study applies, even if different approaches take place at locations other than the trial site itself
- Decentralised elements are considered as new approaches. Therefore, sponsors are encouraged to describe the implementation of these steps in more detail compared to traditional study protocols
- The use of decentralised elements shall be justified and considered in the protocol's risk-benefit assessment

Continued work

- The Swedish MPA will continue to have a supporting role for the issues over which the agency has direct influence at a national level and to work with decentralised clinical trials on EU level

- The Swedish MPA will also continue to provide regulatory guidance on decentralised elements in clinical trials

The Project webbpage & Contacts

- https://www.lakemedelsverket.se/en/permission-approval-and-control/clinical-trials/medicinal-products-for-human-use/decentralised-and-virtual-interventional-clinical-trials

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