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Patient centric, decentralized and virtual clinical trials – a national project

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Decentralised investigational clinical trial

- A decentralised interventional clinical trial can be described as a method for, with the help of digital aids, 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 is expected to contribute to:

- 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

How can interventional clinical trials be carried out decentralised in Sweden?

Feasibility study - 2020

- Two rounds of workshops with all national stakeholders
- Five pilots included
- Prompted start of discussions and quality assurance within the agency
- Regulations, guidelines and established practices have been analysed by the agency and a dialogue has been established with various actors
  - → We can state that there are no formal obstacles to conducting clinical trials in this way linked to the regulations as part of the Medical Products Agency's assignment

The Pilots

- One trial in phase I, one trial in phase III and three trials in phase IV
- Indications include diabetes, covid-19 and breast cancer
- Steps we follow:
  - electronic consent at a distance
  - home sampling administered by the patient himself
  - distance visits within the framework of the trial
  - medical device solution to capture symptoms of side effects
  - distribution of trial drugs
  - medical device solution to register adherence to treatment.

The project deliverables

- The pilots will be followed until “end-of-trial”
  - Interviews with investigators and sponsors
  - Gather best practice, do’s and don’ts
- Continuously publish Q&A at the MPA website in support of DCTs
- Still an opportunity for a certain number of free advice - **contact us!**
- MPA will contribute our experiences and collaborate with relevant EU groups

Swedish Medical Product Agency - General considerations on DCT

- 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 or reduced risk or burden for patients
    - Cost efficiency is not an acceptable reason to introduce decentralised elements
- 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 taken into account in the protocol's risk-benefit assessment

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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