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Patients‘ perspective on Decentralised Clinial Trials

Christine Dehn
Manager Patient Representation
Amsterdam, 23 Nov 2023

Recommendation Paper

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RECOMMENDATION PAPER ON DECENTRALISED ELEMENTS IN CLINICAL TRIALS

Drafted in a collaboration between the **HMA Clinical Trial Coordination Group** (CTCG), **EC Clinical Trial Expert Group** (CTEG) and **the EMA GCP Inspectors Working Group** (GCP-IWG).

https://health.ec.europa.eu/system/files/2023-03/mp_decentralised-elements_clinical-trials_rec_en.pdf

Meaningful involvement

Sponsors and investigators should engage potential trial participants, patients or patient organisations in a meaningful participatory process that involves them in an early and sustained manner in the design, development and implementation of the clinical trial.

➔ Ensures that the protocol is fit for purpose, feasible and can be implemented by all parties.

Patients‘ ability to contribute

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Any transfer of burden of trial related procedures to trial participants and/or investigators **should be weighed against the potential benefits of using decentralised elements** in the clinical trial.

➔ In general, DCT elements should be as simple and easy as possible for the patient. One aspect mustn’t be neglected:
Patients go through various stages in their disease. If they have a good day, they will be able to comply with challenging things, on bad days, this might not be the case.

Reimbursement

The sponsor should provide **in the clinical trial application a description of the funding of the clinical trial and any other (financial) arrangements between funder, investigator and service providers** involved in the conduct of the clinical trial.

➔ This is a very important aspect. If patient has to do additional tests with local health care providers, reimbursement and costs should be defined upfront. It should not be the patient's task to fight for any extra services.

Limitations of target population

Potential exclusion of digitally illiterate persons or people who live in areas with **limited internet connection**

➔ Yes, but also population groups can be included that otherwise will not have the flexibility to go to physical appointments at the trial site on a regular basis. Decentralised participation in the study is easier to integrate into everyday's life, which is very convenient for people who work and are very involved in their families.

Concrete action plans

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The trial **participant should be well informed and receive contact details for all necessary situations** including who to contact for acute cases, but also for device failures, questions on home visits, etc.

➔ It is very important to advise the participant not only on his tasks, but also give him "emergency plans". He has to understand how to react in different cases. He should be able to understand if this is something that needs extra monitoring, but is not worrying or is this a situation that requires immediate action (call 112 or go to the hospital).

➔ Participant has to be aware that his data might not be reviewed in real time.

(Severe) adverse events

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The priority is to **capture and assess SAEs** in a timely manner, **without creating an unacceptable burden** for the investigator and/or the trial participant.

➔ The patient should never have the feeling to cause burden or extra work to the investigator if asking (especially in the beginning) questions. Insecurities especially in older and fragile populations have to be dealt with patience and guidance.

Good communication

Good communication between the investigator and the trial participant is **beneficial for mutual trust** and may **promote trial compliance**.

➔ And if not the investigator himself, another staff member should be assigned for this task. The patient should always have the chance to personally talk to someone (no fluctuation like in a service hotline).

Reality among patient groups?

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Consultation of German CVD patient groups in summer 2023:

- Most patients have never heard of decentralised clinical trials. A few already knew about the topic from the press, but have never participated in such a study.
- Very few patients were approached by their treating physicians. In the positive case, most of the doctors themselves cooperated in the study. Other recruitment took place in the waiting room or through own research.
- About a quarter of the patients have experience with telemedicine. If explained in more detail, mostly defi patients. This is perceived as great additional security.
- Almost all patients either use a smartwatch, enter values into an app or note down their values (digitally in an Excel spreadsheet or in a notebook).

Reality among patient groups?

- Most patients can imagine participating in such a study. Some patients who are against it would also not take part in a classical study, because participation in a study would generally be associated with too much risk.
- They welcome the less time required, because there is no need to travel or wait, and participation in the study is easier to integrate into everyday life. They see the more frequent checks (by the doctor, but also by themselves) as positive and hope for advantages in terms of health and life expectancy.
- A surprisingly large proportion want to contribute to research and give something back because they have benefited themselves.

Reality among patient groups?

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- Through DTC, researchers would have a wider reach (local), be able to reach a wider group of participants (socio-economic). Thus, the data would be more robust. Participation in a study is no longer dependent on place of residence. However, the question remains how patients can find out about the possibility of participating in a study.
- Some patients hope for faster approval and more advanced care.
- One patient stated that he hoped that the study situation in less well researched topics could be improved.

Reality among patient groups?

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- But: Most patients fear **losing personal contact** with the doctor.
- One patient remarked that patients might not take participation in the study as seriously because there is less effort involved. **The appreciation and conscientiousness could decrease.**
- The **exclusion of the older patient groups who are not confident in using digital tools** was seen as problematic.
- Several patients expressed concerns about a **potentially very time-consuming protocol.**
- - Privacy and ethical review are important to many, but fewer overall than expected (using e.g. Whatsapp already).

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Thank you for your attention.