DCT – prespective from Finland

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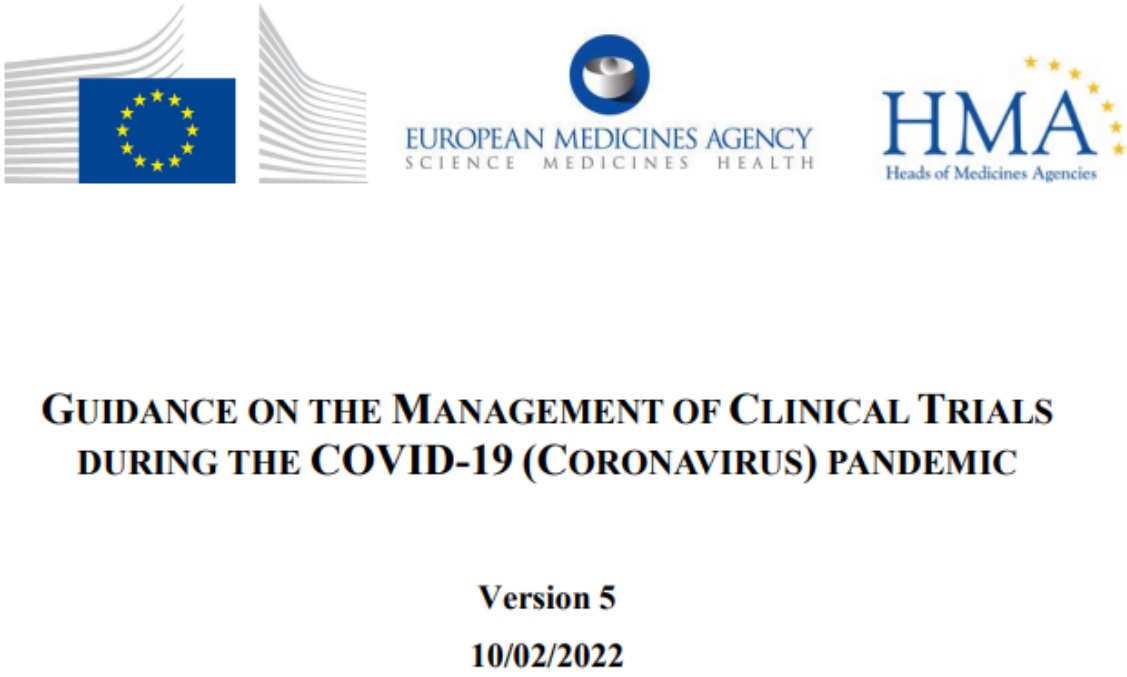
DCT in the EU

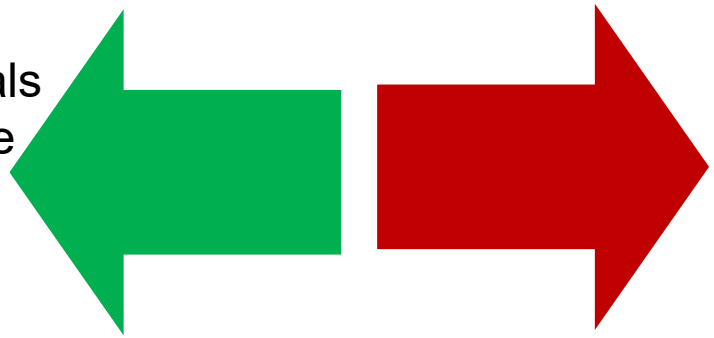
- Due to Covid-pandemic, changes to the conduct towards DCT were made for ongoing CTs, regulatory guidance was prepared and has been updated*
- EU DCT project (EU regulatory groups involved: CTCG/CTEG/GCP IWG) recommendation paper '*initiation and conduct of clinical trials using DCT elements' planned to be published Q4/22*



*https://ec.europa.eu/health/system/files/2022-02/guidanceclinicaltrials_covid19_en_1.pdf

Justification of decentralized elements

DCT approaches can be particularly suitable for trials with chronic diseases, rare diseases, immobile participants, self-administrable IMP, lower safety risk profile, and confirmatory CTs

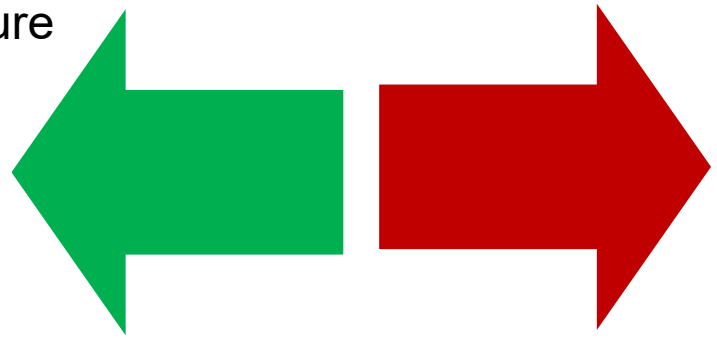


Insufficiently detailed description and justification of decentralized elements in the protocol

DeJong et al :Opportunities and Challenges for Decentralized Clinical Trials: European Regulators' Perspective de Jong AJ, et al. Clin Pharmacol Ther. 2022. PMID: 35488483

Sponsor and investigator responsibilities

Home health visits to ensure proper oversight and detection of safety events



Participants becoming responsible for communicating safety information
Inappropriate delegation of tasks

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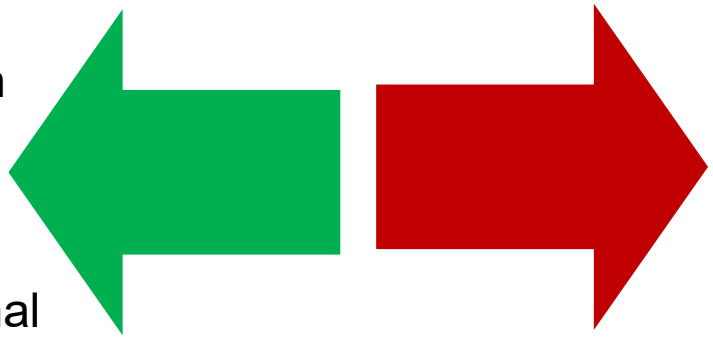
Trial subjects´intrests

Less burden
Larger geographical reach
Improved accessibility by recruiting participants that would not normally participate in a conventional CT



Insufficient relationship building with participant
Inability to assess participant's ability and eligibility to participate
Increased workload for participants and investigators

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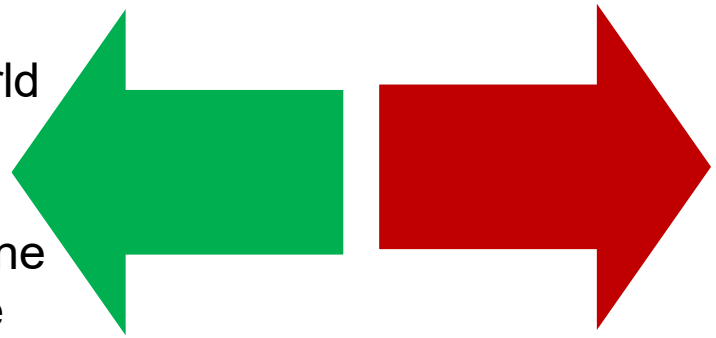
Data quality

Collection of continuous data closer to the real-world setting
More complete data by enabling home/telemedicine visits, and by reducing the data collection burden



Recruitment of a skewed population
Difficulty interpreting large datasets
Limited validation of novel digital outcome measures

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Current status and the near future

- Areas of regulatory focus
  - Remote informed consent process – rights of the trial participants; justification (incl description of data protection arrangements) needed, strong identification method (electronic signature OK)
  - Collection of adverse events, appropriate medical treatment and follow-up of trial participants
  - Data quality, computerized systems (EMA draft guideline 226170/21*)
  - IMPs: investigator responsible for drug accountability. According to national legislation, direct from sponsor to patient -supply of IMPs is prohibited (lääkelaki 32§)
- Hybrid approach?
- FAQ on DCT for Fimea´s website in preparation
- Dialogue between sponsor and regulatory authority

*https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/draft-guideline-computerised-systems-electronic-data-clinical-trials_en.pdf