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

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.

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
Trial subjects´interests

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

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

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