Ethics review of Decentralized Clinical Trials (DCTs)
Results of a mock ethics review

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Background

Decentralized Clinical Trials (DCTs) aim to make trials more efficient, patient-friendly and accessible, by using digital innovations to center trials around participants

Obtaining ethical approval is essential for realizing the opportunities offered by DCTs

Aim

To gain **insight into the ethics assessment of DCTs**

An overview of relevant aspects of the ethics review of DCTs can **facilitate future guidance on ethics review of DCTs**

Methods

Members of European ethics committees (ECs) and competent authorities (NCAs) discussed and reviewed a fictitious randomized fully DCT protocol as a case study in three 'mock ethics review' focus groups

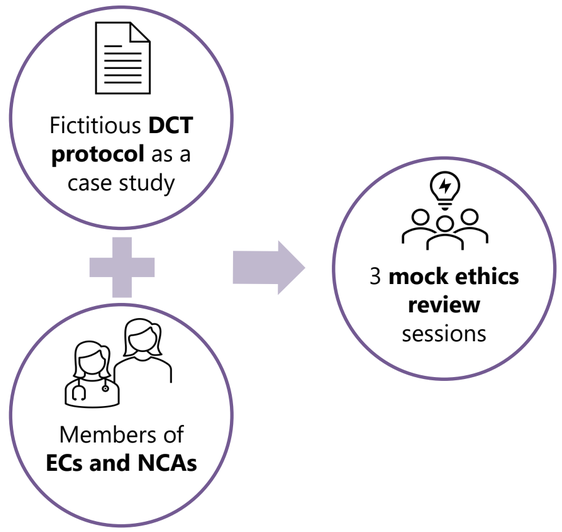
Results

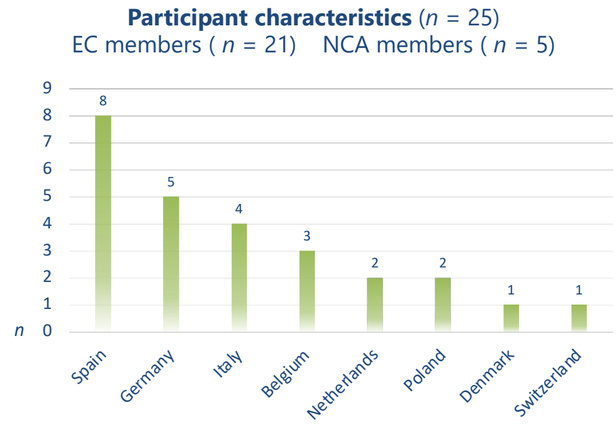
I Social value and scientific value
- DCT approach requires additional justification of rationale and design
- Impact on data quality

II Fair subject selection
- Potential inclusion bias due to technical requirements

II Risks, burdens and benefits
- Transfer of burden, control and responsibilities towards patients
- Additional safety risks perceived for DCTs
- Need for clear description of oversight and responsibilities
- Data protection issues

III Informed consent
- In-person contact important for informing participants and strengthening trust and motivation
- Physical examination deemed necessary





Conclusion

Generally hesitant attitudes towards DCT approach and preference for regular CTs or hybrid approaches

High standard of safety maintained and tendency to risk-aversiveness

More fundamental themes in **researcher-participant relations** – trust, motivation, and transfer of responsibilities – need further research and ethical reflection

Equal attention is needed for **positive and participant-friendly aspects** in ethics assessment to benefit from the opportunities offered by DCTs

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