EU Recommendations on Decentralised Elements in Clinical Trials

Joint Meeting of the CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients and Consumers Working Party (PCWP)

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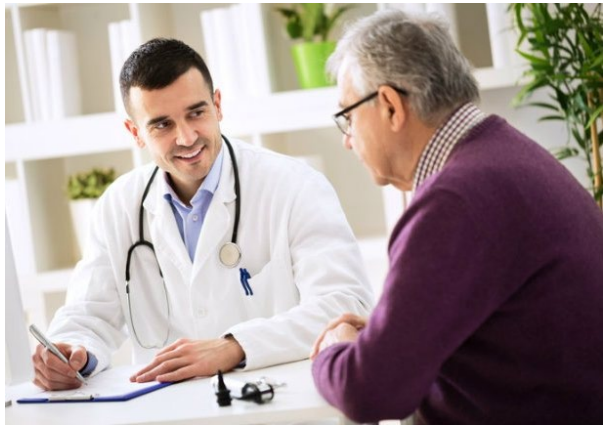
Decentralised elements (DCT)

The DCT approach seeks to take advantage of the technological progress and introduce new methodologies to make clinical trials more easily accessible and participation more convenient for trial participants.

- **Home health visits** to the trial participant's home and teleconsultation,
- **Electronic informed consent** procedures with remote consent.
- **Direct shipment** of investigational medicinal products (IMPs) to trial participants home

- ➢ Flexibility for trial participants
- ➢ Less direct interaction between investigator and trial participants

Focus of the DCT recommendations



Opportunities ⟷ **Challenges**
manage and mitigate

- Trial participant-centred and risk-based approach
- Investigator and sponsor oversight
- Reliable and robust data fit for purpose

DCT recommendations - Content

1. Introduction, scope and **general considerations**
2. **Clinical trial oversight**: roles and responsibilities
3. **Informed consent process**
4. **Delivery of medicinal products** and administration at home
5. Trial related **procedures at home**
6. **Data collection and management** including defining and handling **source data**
7. **Trial monitoring**

Clinical trial oversight - challenges

↓ On site visits

↑ Involvement of service providers

↑ Use of electronic systems

↑ Amount of incoming data: wearables, home nursing, patient reported outcomes, etc.

More tasks delegated - responsibilities same (ICH E6 GCP)

Mitigate: **Ensure that sponsor and investigator are able to keep oversight on trial paticipant safety and well-being.**

Involve patient organisations and investigators:

→ **implementation according to trial participant and investigator needs**

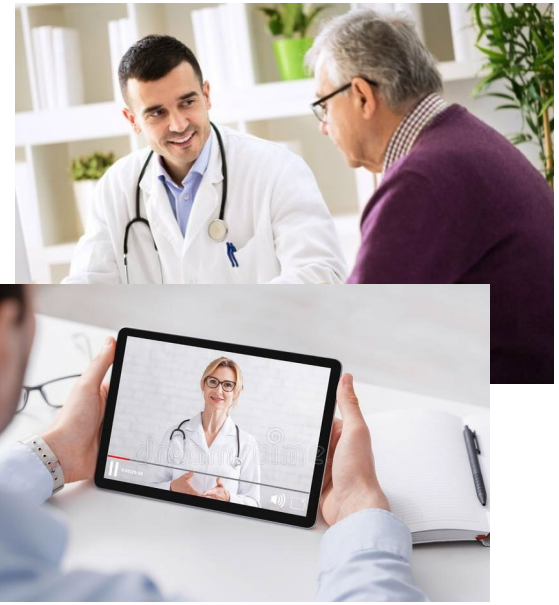
Clinical trial oversight: Clear roles and responsibilities

→ **Document** which tasks are conducted at what place, when, and by whom and how oversight is maintained.

→ Clear **communication plan** between the different parties involved: sponsor, investigator, participants, service providers.

→ Trial **participants informed** on information flow and how to make contact for acute safety concern, device malfunction or other questions.

Informed consent process



Participant-centered approach: Tailor to trial and population

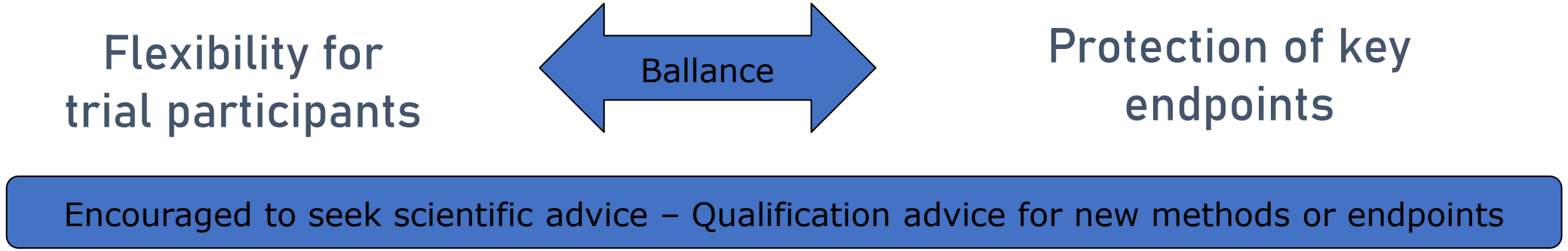
→ **Step-by-step description** of procedure including selection and evaluation of eligibility. This in general, includes a **physical meeting**.

Remote interview may be justified depending on vulnerability of trial population, knowledge on efficacy/safety profile and complexity of trial – then face-to-face real-time videocall.

Informed consent not only of ethical and legal importance: good communication between investigator and trial participant creates mutual trust and promote trial compliance

Use of data for marketing authorisation?

- **Potential differences** between study population and target population.
- Imposed modifications in outcome assessments that my challenge validity e.g. **heterogenous implementation** of DCT procedures across sites or participants.
- Potential increase in **missing data** – overall or for specific endpoints.



Thank you for your attention