European Federation of Pharmaceutical Industries and Associations

Decentralised clinical trials, new directions

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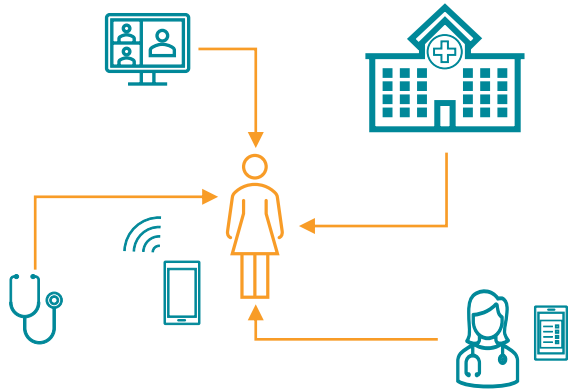
Acknowledging input from many industry colleagues

Decentralised clinical trial model - bringing the trial to the participant



- **Some or all of the assessments undertaken local to the participant or remotely**
- **The trial is organised around the participant & considers the needs of the site**
- **Providing options, reducing burden & facilitating participation**
- **Facilitating innovative, meaningful data collection & novel endpoints using Digital Health Technologies (DHTs)**

Challenges

- **Operational & Technology**
  - Data consolidation and complexity of data flows
  - Potential for selection bias
  - Impact on existing operations
  - Assessing service provider suitability & competency in DCTs
- **Responsibilities & oversight**
  - Participant - Investigator relationship
  - Investigator supervision of participants & distributed care team
  - Reporting and handling of potential AEs/SAEs
  - Site & participant training & acceptance of use of DCT elements
- **Data privacy/protection**
  - Maintaining privacy and protection of personal information
- **Data quality**
  - Comparability of data for site & remote assessments
  - Data acceptability & management of large data sets
- **Regulatory framework**
  - Emerging regulatory guidance globally - opportunity for further alignment
  - Fragmentation - adaption required according to local laws & regulations e.g. electronic signatures

EU recommendation paper on decentralised elements in clinical trials

Informing a harmonised approach

- Facilitates the use of decentralised elements in clinical trials, whilst protecting the rights, safety and well-being of participants and reliability of trial results.
- Provides an informative summary of how DCT elements can be incorporated, with the National Provisions Overview helpful for navigating across Member States.
- Evolution as new insights and experiences are gained is important, given the rapid advances in the field.

Proposed topics for future updates

- **Locations that differ from traditional clinical trial site:** Expand broader than 'home' e.g. local Health Care Professional/ General Practitioner, local laboratories, mobile health units.
- **Data variability & acceptance:** How to measure differences between clinic and remote assessments, how to ensure data integrity & quality, regulator expectations.
- **Digital Health Technologies:** How to get DHT derived endpoints accepted faster, understanding key validation criteria, collection & use of participant data, expectations for availability of meaningful data.

Considerations towards a shared future vision

EU harmonisation: Consider how the National Provisions Overview could be maintained and iterated upon in a timely manner, and made easily accessible.

What efforts are ongoing on a local level to enable DCT elements to be implemented in EU countries where current local laws prohibit? Could we envision EU harmonisation?

Global alignment: Consideration of future alignment/harmonisation with draft FDA guidance, and globally e.g. ICH E6(R3).

How can we work towards global alignment/ harmonisation?

Building upon experience: Sharing of experiences, lessons learnt & views is needed across stakeholders. Consider how to systematically evaluate the impact of DCT elements on data quality and integrity.

What is needed to further explore the impact of DCT elements vs standard CTs? How can we further share experiences?

All parties have the same aim - participant rights, safety & well-being, and data integrity for reliable trial results

Future vision: Decentralised elements become part of the clinical trial toolbox, deployed depending on the scientific question, patient population & needs, for patient-centric trials, more accessible to under-represented populations.

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Thank you