28/11/2022
EMA/921051/2022

Workshop outcome - ACT EU Multi-stakeholder Meeting on Decentralised Clinical Trials

October 4, 2022 | 9:30 – 17:00 pm CET
Onsite meeting at EMA with broadcast of plenary sessions

Meeting Overview
The purpose of the meeting was to discuss subjects related to decentralised clinical trials (DCT) with the scope to provide input to the upcoming recommendation paper from the European Medicines Regulatory Network (EMRN). The meeting was planned by the EU DCT project team as part of the Accelerating Clinical Trials in the EU (ACT EU) initiative and hosted by the EMA. The main outcome of the meeting is direct incorporation of external stakeholder inputs into the recommendation paper targeted for publication at the end of 2022.

Themes

- Authority perspective with focus on clinical trial authorisation representing the perspectives from the MSs competent authorities (CTCG), ethical authorization (CTEG) as well as GCP inspectors (GCP IWG).
- Sponsor and CRO perspective.
- Investigator site and patient perspective.
- Targeted breakout discussions

Presentations
Introduction and Authority perspective
The DCT approach aims to make clinical trials more easily accessible and participation more convenient for trials participants. Examples of DCT elements are home health visits, shipment of IMP to participants and electronic informed consents. The DCT recommendation paper will include an appendix of a national overview clarifying related national provisions. The topics in the recommendation paper were summarized.

Sponsor and CRO perspective
EFPIA pointed out that their understanding is that in the future we will not talk so much about traditional, hybrid or DCT but instead DCT elements will become part of the clinical trial toolbox.

EORTC shared the experiences from an academic sponsored clinical trial using DCT elements.

Solutions to identified challenges with DCT were presented by EUCROF and ACRO informed about their tool kit to help DCT setup.

Patient and Investigator Perspective
From a patient perspective it was outlined that patients should make their own choice and that hybrid trials could be the preferred way.

From an investigator perspective, the increased data flow giving both possibilities and challenges was pointed out.

Panel discussion to explore patient and investigator site perspective
The relation between the patient and investigator is key and a face-to-face meeting in the beginning of most trials will probably often be preferred.

Breakout session discussions
1) Sponsor and investigator oversight ensuring patient care, treatment and safety when conducting procedures at home
The discussions focused on third parties contracted by sponsors for activities under the investigator's responsibility. The use of platforms or other computerised systems was discussed as well as the importance of handling the data in a relevant way.

2) IMP shipment to patient's home
Experiences from different ways of distribution if IMPs were shared. As the national legal frames are different in this area, IMP shipment will be included in the national overview as an appendix to the recommendation paper.

3) Electronic Informed consent
The discussion included pre-screening, meeting between patient/investigator, identification of the patient and use of electronic signatures.

4) Defining and handling of source data and remote monitoring
Different views of what is meant by source data and how it is controlled and what needs to be maintained were given. Remote source data verification was discussed linked to the confidentiality of the personal data, data security and secured access to the data.

5) Other relevant issues and opportunities for use of decentralised elements in clinical trials
Main topics raised were use of data for marketing authorisation and the concept of fully decentralised clinical trials.

Conclusion
Input from the meeting was directly implemented to improve the recommendation paper and ensure usefulness for stakeholders within clinical trials.