12 August 2022
EMA/28670/2022

ACT EU Multi-stakeholder Meeting on Decentralised Clinical Trials

4 October 2022, 09:30-17:00 CET

Background and objectives

Decentralised clinical trials (DCTs) introduce new approaches to the conduct of clinical trials that aim to make clinical trials more easily accessible and convenient for participants to take part in. The DCT methodology is based on elements such as home health visits, direct to patient shipment of study drugs and electronic informed consent.

The ACT EU Programme will host a multi-stakeholder workshop on DCTs on behalf of the EU DCT project, bringing together participants from all areas of the research community to share perspectives on this type of clinical trials. The multi-stakeholder workshop will be hosted by EMA on October 4th 2022. The onsite workshop is open to invited participants only. A live broadcast of the workshop's plenary session will be provided, open to all interested parties.

During the workshop, the EU DCT project group will present the work of the European Medicines Regulatory Network on decentralised clinical trials collaboration, including the planned publication of a guidance paper on the use of decentralised elements in clinical trials in Q4 2022. The workshop will include breakout sessions with an opportunity for shared discussion on topics of relevance to DCTs facilitated by the core members of the EU DCT project team, consisting of clinical trial experts from the Clinical Trials Coordination Group (CTCG), ethical experts from the Commission Expert Group on Clinical Trials (CTEG) and Good Clinical Practice (GCP) inspectors from the Good Clinical Practice Inspectors Working Group (GCP IWG).

The workshop aims specifically to bring forward the perspective of patient representatives and investigator site experts with the agenda outlined below.

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ACT EU Multi-stakeholder Meeting on Decentralised Clinical Trials

Introduction

09:30 – 09:50	**Welcome and opening remarks** *Greet Musch (FAMHP/CTCG)* *Peter Arlett (EMA)*	*10'*
	Scope of the EU DCT collaboration across the European Medicines regulatory network *Ditte Zerlang Christensen (DKMA)*	*10'*

Authority Perspective

09:50 – 10:30	**EU DCT recommendations from the European Medicines regulatory network** *Solange Levison (CCMO)* *Monique Al (CCMO)*	30'
	Q&A	10'

Sponsor and CRO Perspective

10:30 – 11:20	**Industry sponsor perspective: Opportunities and challenges for the use of DCT elements in clinical trials** *Alison Bond (EFPIA)*	10'
	Academic Sponsor perspective: Experiences on use of DCT elements during covid-19 *Vassilis Golfinopoulos (EORTC)*	10'
	CRO Insights and Experiences: How to solve identified challenges on the implementation of DCT elements in clinical research *Yoanni Th. Matsakis (EUCROF)* *Fiona Maini (ACRO)*	15'
	Q&A	15'

11:20 – 11:40 **Coffee break**

Patient and Investigator Perspective

11:40 – 11:50	**Patient perspective** *Julián Isla (COMP and Dravet Europe)*	10’
11:50 – 12:00	**Investigator perspective** *Dr Filippo Pieralli (University Hospital Careggi)*	10’
12:00 – 12:50	**Panel discussion to explore patient and investigator site perspective.** *Panellists:* *Sally Hofmeister (World Duchenne Organization)* *Julián Isla (COMP and Dravet Europe)* *Aisling Walsh (EFCNI)* *Mira Zuidgeest (trials@home)* *Dr Filippo Pieralli (University Hospital Careggi)* *Dr Francisco Bautista (Princess Máxima)* *Moderator:* *Kasper Bendix Johnsen (Danish National Center for Ethics)*	

Closing remarks

12:50 – 13:00	**Closing remarks for plenary sessions and broadcast** *Greet Musch (EU DCT steering group)* *Peter Arlett (EMA)*	10’

13:00 – 14:00 **Lunch**

Breakout sessions

14:00 – 14:45	**Breakout topics** 1) Sponsor and investigator oversight ensuring patient care, treatment and safety when conducting procedures at home 2) IMP shipment to patient's home 3) Electronic Informed consent 4) Defining source data and remote source data verification (rSDV) 5) Other relevant issues and opportunities for use of decentralised elements in clinical trials	**45'**
14:45 – 15:15	**Coffee break**	**30'**
15:15 – 16:00	**Breakout topics** 1) Sponsor and investigator oversight ensuring patient care, treatment and safety when conducting procedures at home 2) IMP shipment to patient's home 3) Electronic Informed consent 4) Defining source data and remote source data verification (rSDV) 5) Other relevant issues and opportunities for use of decentralised elements in clinical trials	**45'**
16:00 – 16:30	**Coffee break**	**30'**

Feedback from Breakout Sessions

16:30 – 16:50	**Summary from Breakout sessions** *Breakout leads*	**25'**

Conclusion and Closing remarks

16:50 – 17:00	**Wrap up** *Greet Musch (FAMHP/CTCG)* *Peter Arlett (EMA)*	**10'**

Information on break-out sessions:

The break-outs are tailored to discuss the regulatory frames, which is being drafted by the EU DCT project team in the upcoming recommendation paper on use of decentralised elements in clinical trials (targeted for publication end Q4 2022). The break-out sessions will be facilitated by EU DCT project team members mainly covering clinical trial authorisation experts, ethical experts and GCP investigators. The scope of all sessions will be to discuss challenges within the subject area with the purpose to identify appropriate risk mitigations and risk-based approaches.

1) Sponsor and investigator oversight ensuring patient care, treatment and safety when conducting procedures at home

The aim of this break-out will be to discuss the considerations associated with the topic of oversight: how to ensure that the responsibilities of both sponsors and investigators remain clearly delineated when procedures are conducted at home and potentially by external stakeholders in accordance with ICH GCP guidelines. Particular areas of interest will include medical care of patients, safety monitoring and home investigational medicinal products (IMP) administration. Practical aspects such as communication between all parties, contractual arrangements and use of local laboratories may also be addressed.

2) IMP shipment to patient's home

The aim of this break-out will be to discuss the considerations associated with shipping IMP to patient's home as well as accountabilities including for storage and destruction. It will cover which factors should be considered and justified if such a shipment is planned in the frame of a clinical trial. Expectations regarding dispensing, blinding, transport, receipt, storage, training, communication, drug accountability, compliance and confidentiality of trial participant's details, among others, will be discussed.

3) Electronic Informed consent

This break-out will focus on the considerations associated with using digital media to deliver information to prospective trial participants and obtaining a written informed consent electronically. Specific areas of attention including potential bias, confidentiality, electronic system characteristics, archiving and communication between the investigator and the potential trial participant will be highlighted and discussed. Advertisement, decentralised recruitment and pre-trial electronic screening of trial participants may also be addressed.

4) Definition and handling of source data and (remote) monitoring

This break-out will cover two topics. The first part will relate to the definition, generation and handling of source data (processing, analysis, quality, compliance, etc.) when using electronic systems or eCOA/wearables as well as when protocol visits/assessments are conducted outside of the clinical site. Second, drawing from the experience of the COVID-19 pandemic, the sustainability and factors to consider regarding remote access to source data for verification/review and monitoring approach will be discussed.

5) Other relevant issues and opportunities for use of decentralised elements in clinical trials

This break-out will be an opportunity to address additional issues relevant to decentralised clinical trials not covered in one of the above areas and may form the basis for future update of the recommendation paper on the use of decentralised elements in clinical trials. The session facilitators will have a broad background and also be able to cover questions on bias and use of data for marketing authorization on a general level. It will be up to the session participants to pose the subjects for discussion in this session.