29 September 2022
EMA/789028/2022

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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Introduction

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

Authority Perspective

09:50 – 10:30	**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** 10’

Julián Isla (COMP and Dravet Europe)

11:50 – 12:00 **Investigator perspective** 10’

Dr Filippo Pieralli (University Hospital Careggi)

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** 10’

Greet Musch (EU DCT steering group)

Peter Arlett (EMA)