The EU Decentralised Clinical Trials project (EU DCT project)

Background:

New and innovative clinical trial designs and methodologies provide opportunities and challenges for the EU clinical trials environment. The EU decentralised clinical trials (EU DCT) project aims to address some of these challenges, in line with the European Medicines Agencies Network Strategy to 2025 and European Commission's Pharmaceutical Strategy for Europe.

In order to facilitate innovation and at the same time ensure safety, dignity and well-being of the trial participant, a cross-disciplinary project group consisting of amongst others clinical trial authorisation experts, ethical experts and Good Clinical Practice (GCP) inspectors across Member States are coming together to develop a harmonised decentralised clinical trial approach from the European Medicines Regulatory Network including ethics committee representatives.

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

Within the DCT approach, various elements may be applied to in a clinical trial depending on context and feasibility. Some DCT elements have already been implemented in the design and conduct of traditional clinical trials e.g. electronic Patient Reported Outcomes (ePROs), electronic (e)diaries and safety follow-up phone calls. Other DCT elements are still under development in many member states and require further regulatory guidance and harmonisation in EU such as:

- Home health visits including teleconsultation and visits where health care professionals come to the trial participant's home,
- Direct shipment of investigational medicinal products (IMPs) to trial participants,
- Electronic informed consent procedures.

Although DCT methodology may offer benefits for the trial participants, in doing so, it also changes the setting in which clinical trials are conducted and the interaction between investigators and trial participants. It is thus essential to assure trial participant's safety, rights and dignity as well as reliability of the generated and reported data in a risk-based implementation of new DCT elements.

Scope and objectives:

The motivation for initiating the EU DCT project is to optimise the EU environment for clinical research in Europe, whilst maintaining high-level participant protection, data robustness and transparency.

The EU DCT project aims to provide a harmonised and transparent approach for the use of DCT elements in clinical trials by the European Medicines Regulatory Network.

The key focus points are implementation of DCT elements with a risk-based mindset and a focus on trial participant perspective ensuring trial participant's safety, rights and dignity. At the same time, the reliability of the generated and reported data has to be maintained.

Deliverables:

The current project was established in March 2022 and builds on previous discussions and experiences in the network.

The project has the following deliverables:

- Key deliverable: Recommendation paper on the use of DCT elements in clinical trials. The recommendation paper is meant to be a living document to be developed as experience and knowledge grow. Targeted delivery is end of Q4 2022.

- DCT workshop hosted by EMA on Oct 4th 2022. The workshop will bring together a broad expert field and has the purpose to discuss the regulatory frames for DCT in EU. It will have the form of plenary session as well as breakout discussions, where the plenary sessions will be broadcasted.

- Overview of differences in national provisions caused for instance by differences in national legislations and infrastructure (delivered targeted with recommendation paper end Q4 2022).

- Implementation of the harmonised position on DCT in the European Medicines Regulatory Network.

Main contributing EU groups:

The Clinical Trials Coordination Group (CTCG) is responsible for project management of the EU DCT project that is conducted within the framework of the ACT EU initiative (priority action 8).

The project incorporates the opinions of the following groups:

- Clinical Trials Coordination Group (CTCG)
- Expert Group on Clinical Trials (CTEG)
- Good Clinical Practice Inspectors Working Group (GCP IWG)

The project represents a broad collaboration across the European Medicines Regulatory Network, and contribution is also provided by volunteering members of:

- Scientific Advice Working Party (SAWP)
- Methodology Working Party (MWP)
- Paediatric Committee (PDCO)
- European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)
- Patients and consumers working party (PCWP)
- Health care professionals working party (HCPWP)