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Experts Want To Drop Confusing Terminology For Decentralized Clinical Trials

by Vibha Sharma

A new scientific paper drawn up by experts on behalf of the EU public-private Trials@Home project discusses the pros and cons of various terms being used to refer to decentralized clinical trials and suggests a unified way forward.

While there is a growing interest in the adoption of decentralized elements in clinical trials, in which activities are centered around study participants rather than investigator sites, the lack of standardized terminology for such research can hamper meaningful discussions on this front.

A new *paper*, published in the scientific journal *Drug Discovery Today*, proposes doing away with terms like “remote” or “virtual” trials when referring to a decentralized trial (DCT), which it says should be understood as an “operational model,” independent of trial methodology.

The paper advocates the consistent use of a unified term, “decentralized clinical trial,” to refer to an operational trial model in which activities are centred around participants, typically enhanced by health technologies. It gives a detailed description of what a DCT might typically entail and states that a “consensus on its use and understanding of its meaning will aid in harmonising future discussions on this topic within the clinical trials arena.”

The use of varying terms – eg, internet- or web-based, patient-centric, site-less or digital trials – can cause confusion over what a particular trial model entails and for what purposes it can be used, hampering discussions on its acceptability and suitability, argue the trial experts who wrote the paper on behalf of the Trials@Home consortium.

The consortium is funded under the Innovative Medicines Initiative, a public private partnership between the EU and the European pharmaceutical industry body EFPIA. A key project of the

consortium involves running a methodological trial comparing the scientific and operational quality of DCTs with traditional trial approaches. (Also see "[Decentralized Trial Approaches: How Do They Match Up To Conventional Studies?](#)" - Pink Sheet, 11 Nov, 2022.)

For the paper, the experts undertook a literature review of previously used terms for trials incorporating decentralized elements and found that these focused either on the use of technology, the trial participant or the location of trial conduct. Many of the analyzed articles mentioned the interchangeability of the terms “virtual,” “digital” and “remote,” but the paper notes that “each term is slightly different, and subtle distinctions are expected to be a source of confusion.”

While “remote,” “virtual” and “decentralized” are the most commonly used terms when referring to DCTs, the paper explains that they can have different meanings. The term “virtual” trials, for example, has been used to describe not only technology-enhanced clinical trials involving participants, but also computer-modelled or *in silico* trials in which there are no actual participants. (Also see "[Why 2020 Saw The Steady Rise Of In Silico Trials](#)" - Pink Sheet, 7 Jan, 2021.)

Moreover, both “decentralized” and “virtual” trials have been used to describe studies with a “more pragmatic trial design, whereas the operational model of centring trials around participants could also be used for the more traditional explanatory clinical trials, which aim to show the isolated drug effect under strictly controlled circumstances,” it adds.

As for the term “remote” trial, the paper states that it emphasizes the “remoteness” of trial activities, ie, being away from the investigator’s site, administration of the intervention, interaction with study staff and assessment of outcomes.

“As such, this term can be confusing because the activities are not conducted remotely from the perspective of trial participants. Rather, the opposite is typically envisioned, because trial activities are centred around, or moved close(r) to, the participants’ surroundings,” it adds.

While DCTs are centered around the trial participant, the experts said they preferred the term “decentralized clinical trial” over “patient-centric trial” because the latter emphasizes that the trial is designed with the needs and preferences of participants in mind.

“Although this can include the centring of trial activities around trial participants, ‘patient-centric trial’ is used for a much broader scope than moving of trial activities, rendering the term less suitable for describing this new operational approach to trials,” the paper said.

Also, it noted that the term “patient centric” was not inclusive of all possible trial participants, such as healthy volunteers, and may not be preferred by individuals who do not regard

themselves as patients.