Modernising the clinical trial: a shift to decentralised trials driven by advances in technology and catalysed by the COVID-19 pandemic

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Introduction

Across established healthcare systems in Europe and the US, there is growing acceptance from payers regarding the role and potential value of decentralised trials (DCTs). DCTs are remote trials executed through telemedicine and remote data collection with mobile/local healthcare providers, without the need for patients to travel to specific sites.[1,2]

This is driven by unprecedented access to anonymised patient data, increases in computational power advancing analytical capability, increasing openness from regulatory authorities, and a new generation of digital friendly physicians and principle investigators.[1] The uptake of decentralised trials has also been accelerated by the COVID-19 pandemic, with global lockdowns and the closing of trial sites impacting patient enrolment and participation in clinical trials.[1,2]

Objectives

This research explores the current awareness and perception of DCTs amongst payers in the EU4 (France, Germany Italy Spain), UK and US, and investigates the opportunities of DCTs in a post-COVID environment for driving innovation and accelerating patient access.

Methods

An online research programme utilising the Lightning Insights platform was conducted with health technology assessment (HTA) and budget-holding stakeholders in the EU4, UK and US. The research explored the perceptions of the acceptability of DCTs compared to conventional clinical trials and the key opportunities and challenges associated with DCTs for demonstrating value within the evaluation of new medicines. Stakeholders provided insights on the extent to which the COVID-19 pandemic has changed the requirements for the design and execution of clinical trials for new technologies, and potentially increased the acceptability of DCTs in stakeholder evaluations across key global markets.

Results

HTA and budget-holding stakeholders across each market were all partially aware of DCTs (Figure 1). Awareness of DCTs was highest in the UK, reportedly due to exposure in ongoing trials, research funding committees, and recent medical literature.

The methodology of DCTs was considered at least potentially acceptable by all stakeholders, with one-third reporting that the methodology is equally as acceptable as conventional clinical trials (Figure 2).

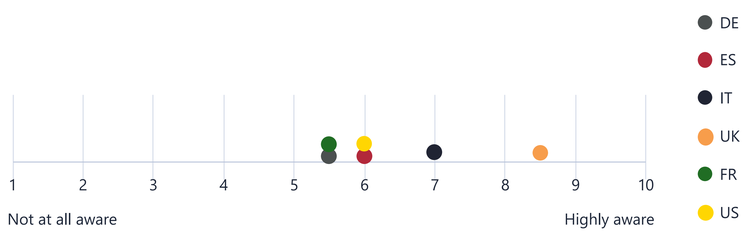


Figure 1. Stakeholder awareness of DCTs as a methodology for clinical development across the EU4, UK and US (from 1-10, where 1 = not at all aware and 10 = highly aware)

References. 1. New Scientist: A Mediaplanet Campaign (2021). Clinical Trials. Available at: https://www.ccra.org.uk/PressReleases_New/Releases/ClinicalTrialsDay.pdf. 2. Dorsey, E. R., et al., (2020). The New Normal in Clinical Trials: Decentralized Studies. Available at: https://onlinelibrary.wiley.com/doi/10.1002/ana.25892. 3. Schliebner, S. & Pruitt, B. (2020). Decentralized Trials: Reshaping the Rare Disease Landscape. Available at: https://s3.us-east-1.amazonaws.com/prahs30-dev-assets/resources/Decentralized-Trials-Reshaping-the-Rare-Disease-Landscape_White-Paper_22OCT2020-2.pdf.

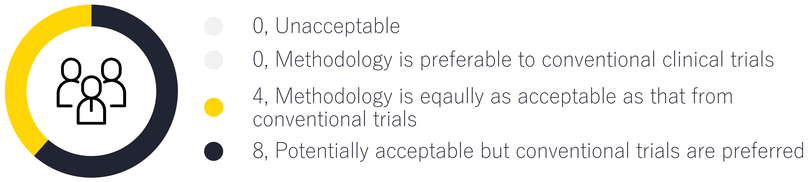
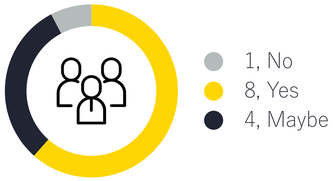


Figure 2. Stakeholder perception of the acceptability of the methodology of DCTs compared to conventional clinical trials for informing payer evaluation

85% of stakeholders agreed that the COVID-19 pandemic has at least somewhat changed the requirements for the design and execution of clinical trials for new medicines (Figure 3).

The greatest change in the acceptability of DTCs due to the COVID-19 pandemic was perceived by stakeholders in the UK, who reported a high change in the requirements for the design and execution of clinical trials to support the development of new medicines.



"The regulatory handling of COVID vaccination has definitely changed the landscape for medicines approval, particularly in the UK"

Former member of SMC, UK

Figure 3. Stakeholder perception on whether the COVID-19 pandemic has potentially increased the acceptability of DCTs for informing payer evaluation

Of the possible opportunities associated with DCTs, increased engagement in clinical trials was consistently considered important across all markets within the study. In the EU4 and UK, this was amongst the highest ranked opportunities alongside accelerating patient access and enabling an increased patient centric approach (Figure 4). Stakeholders in the US considered increased flexibility in protocol changes to be an important opportunity and unlike in the EU4 and UK, ranked accelerating patient access as the lowest opportunity.

Being unable to fully control trials was consistently considered an important challenge across all markets, alongside lack of accessibility for technology naïve patients and a lack of contact with clinicians which could have a negative impact on patient adherence (Figure 5).

Although reluctance to change from regulatory authorities was considered important in the UK, this challenge was considered of lower importance by stakeholders across the EU4 and the US.

Reducing the cost of clinical trials for manufacturers was considered the least important opportunity across markets.

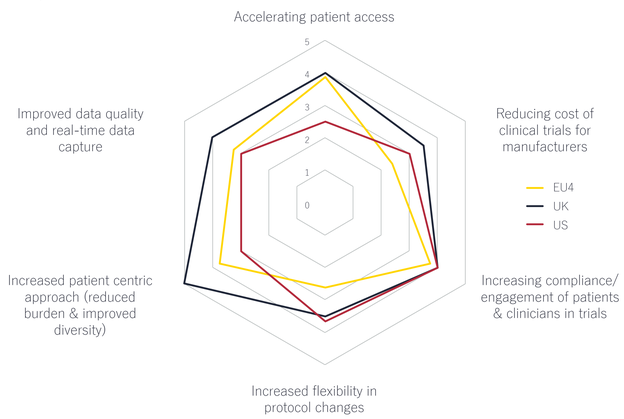


Figure 4. Stakeholder perception of the importance of the opportunities associated with DCTs for the clinical development and value demonstration for new medicines (from 1-5, where 1 = low importance and 5 = high importance)

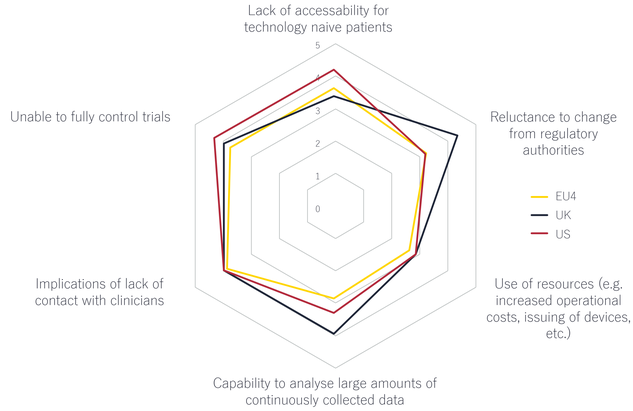


Figure 5. Stakeholder perception of the importance of the challenges associated with DCTs for the clinical development and value demonstration for new medicines (from 1-5, where 1 = low importance and 5 = high importance)

"I think there are merits to this approach. The ability to get real-world like outcomes could be a significant positive. The big challenge is assuring stakeholders that data collected by such devices is valid and reliable"

Former VP, Medical Management, US

Discussion

The landscape for DCTs is evolving

The landscape for conducting clinical trials is evolving post-COVID-19 pandemic, with payers potentially more receptive to consider the methodology of DCTs. However, this varies across key global markets. For example, one stakeholder noted that the French authorities are particularly reluctant to change, whereas with a high awareness and a positive perception of DCTs, the UK may represent the most promising environment for the adoption of these trials.

DCTs show great potential to efficiently track outcomes that limit long-term uncertainty for the growing number of advanced treatments in development, and to support the clinical development for rare diseases, by alleviating the burden of clinical trial participation and helping to democratise clinical trial access.[3]

Efforts must be made to increase education on the benefits of DCTs and reduce reluctance to consider these trials within the evaluation of new medicines

Across all markets, it is important to increase education and awareness around the opportunities associated with DCTs and how potential challenges can be mitigated. Further assessment of the methodology of DCTs and exposure to successfully run DCTs is also required to support the validity and reliability of this approach for regulatory authorities and payers.

To successfully execute DCTs within the clinical development of new medicines, it will be important to set up and utilise new research networks, with engagement of stakeholders across academia, patient organisations, clinical specialists, regulators and HTA/payer bodies, and digital technology providers to support the efficiency and acceptance of this methodology.

Conclusion

Although DCTs may not replace the randomised clinical trial as the gold-standard, the life sciences community may be moving towards greater acceptance of a decentralised approach to clinical development, facilitating increased engagement and diversity in clinical trials, increasing patient centricity and accelerating patient access to innovative new medicines.