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Pharmacoepidemiology and Clinical Pharmacology

Opportunities and Challenges for Decentralized Clinical Trials: European Regulators' Perspective

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INTRODUCTION

Decentralized clinical trials (DCTs) have the potential to improve accessibility, diversity, and retention in clinical trials by moving trial activities to participants' homes and local surroundings, thereby reducing or eliminating on-site interactions with investigator staff. The Covid-19 pandemic has compelled regulators to take a position on the implementation of remote elements in clinical trials (1), and several European national competent authorities (NCAs) have recently expressed interest in DCTs, issuing guidance and conducting DCT pilot studies (2, 3). Nonetheless, few full DCTs have been conducted in Europe thus far. Recent work has suggested that, amongst other factors, regulatory requirements and a perceived 'low degree of acceptance' by NCAs may be limiting their implementation (4, 5). Hence, identifying the opportunities and challenges for DCTs from the perspective of regulatory bodies could help enable progress.

GOAL

To identify regulatory opportunities and challenges for the implementation of decentralized clinical trials in Europe, by interviewing regulators.

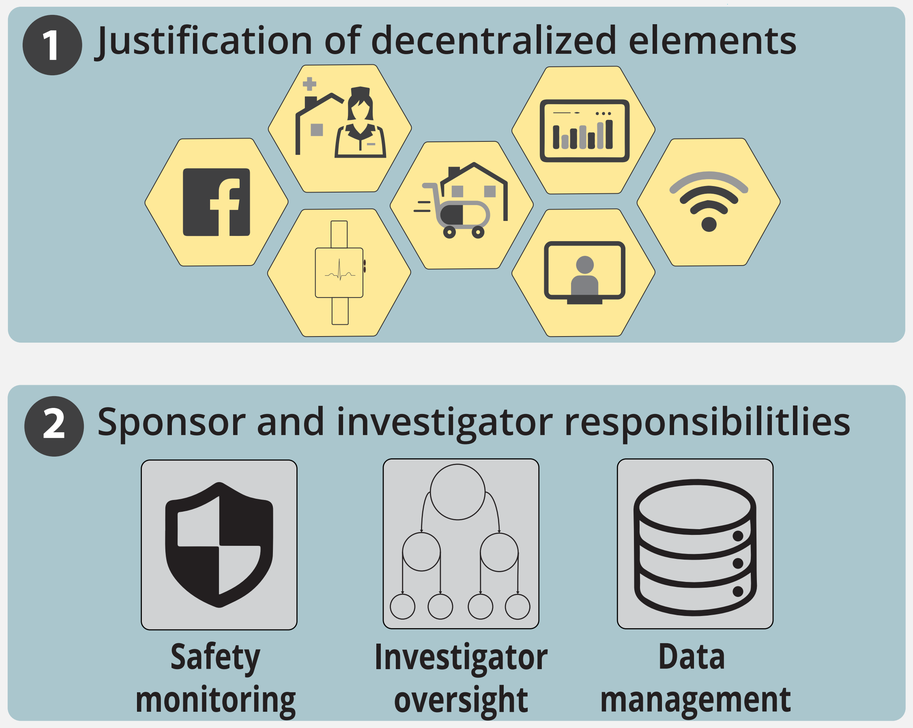
METHOD

15 one-hour, semi-structured interviews were conducted with 20 European regulators including clinical trial assessors, good clinical practice inspectors, and clinical data assessors. Data were analysed following thematic analsyis.

RESEARCH HIGHLIGHTS

- DCT proposals should be **justified** and well-described
- Regulators expect that DCTs will facilitate **recruitment of underserved patient groups**
- Data collected in DCTs are expected to be **more representative** of the real-world
- **Investigator oversight** and **safety monitoring** may challenge DCT implementation
- Future experience with DCTs - to evaluate the impact on safety monitoring - can be exerted through **hybrid clinical trials**

IDENTIFIED THEMES



CONCLUSIONS

Key opportunities of DCTs recognized by the regulators include a lower participation burden, allowing underserved groups to participate in CTs, and capturing data closer to the real world. However, limited physical examinations, and maintaining investigator oversight when involving third parties are challenges to the implementation of DCTs. The impact of decentralization on the data quality should furthermore be addressed when designing a DCT. Considering the factors identified in this study, the EU regulatory network is ready to gain experience with DCTs to make trials more participant-centered.

References 1 - de Jong et al. (2021), 10.1002/cpt.2225. 2 - Danish Medicines Agency's guidance on the implementation of de-centralised elements in clinical trials with medicinal products (2021). 3 - Swedish Medical Products Agency. Decentralised and virtual interventional clinical trials. (2021). 4 - Coert et al. (2021), 10.2196/26813. 5 - Polhelmus et al. (2019), 10.1177/2168479018801566.

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