

Decentralized Trial Activities Reported in Publicly Available Clinical Trial Protocols

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INTRODUCTION

Decentralized trial activities, such as recruitment via social media, data collection through wearable devices, telemedicine and home health visits, and shipment of IMP to trial participants' homes, have the promise to improve clinical trial conduct. For example, these decentralized trial activities could enable more participant-centered clinical trials by lowering the number of required on-site visits.

The Covid-19 pandemic has furthermore increased the interest in and uptake of decentralized trial activities to ensure participant safety and trial integrity. However, there is limited insight in the extent to which decentralized trial activities are implemented in clinical trials.

GOAL

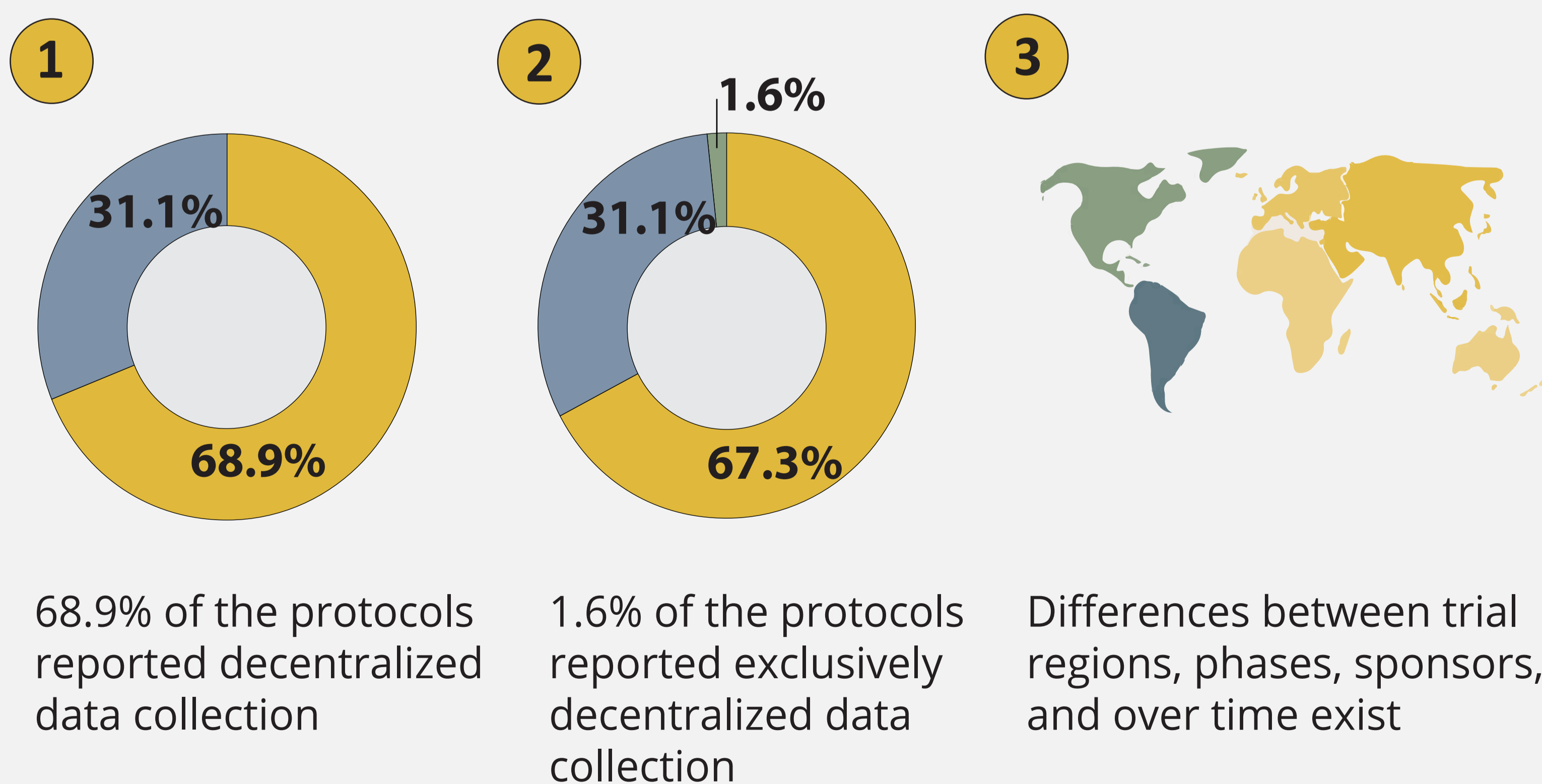
To investigate the occurrence of decentralized and on-site conduct of trial activities as reported in publicly available clinical trial protocols with a study start in 2019 or 2020.

METHOD

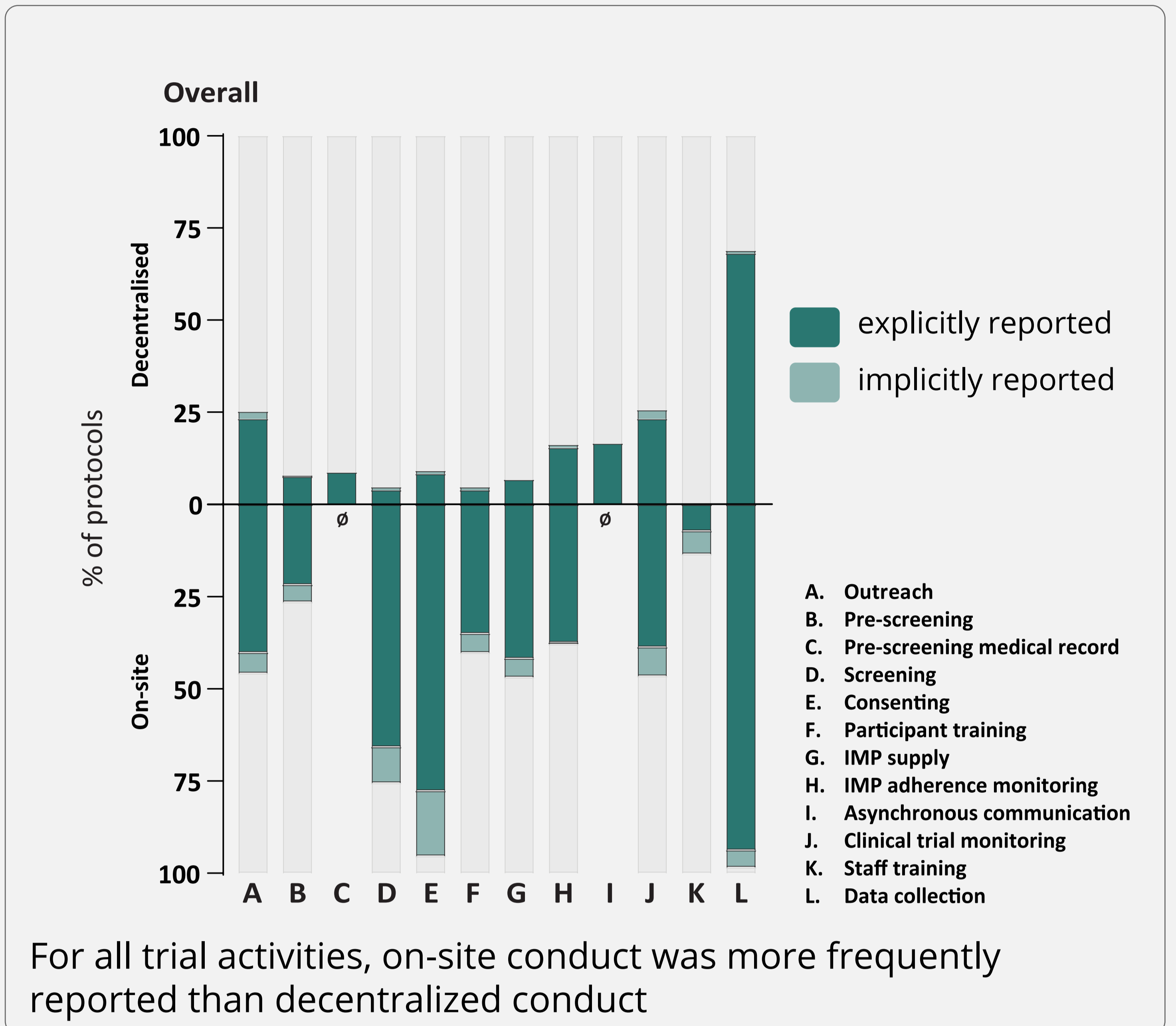
Publicly available protocols from phase 2, 3, 4 interventional clinical drug trials with a start date in 2019 and 2020 were downloaded from ClinicalTrials.gov.

Decentralized and on-site conduct of the following operational trial activities was manually ascertained: participant outreach, pre-screening, screening, obtaining informed consent, asynchronous communication, participant training, IMP supply, IMP adherence monitoring, CT monitoring, staff training, and data collection.

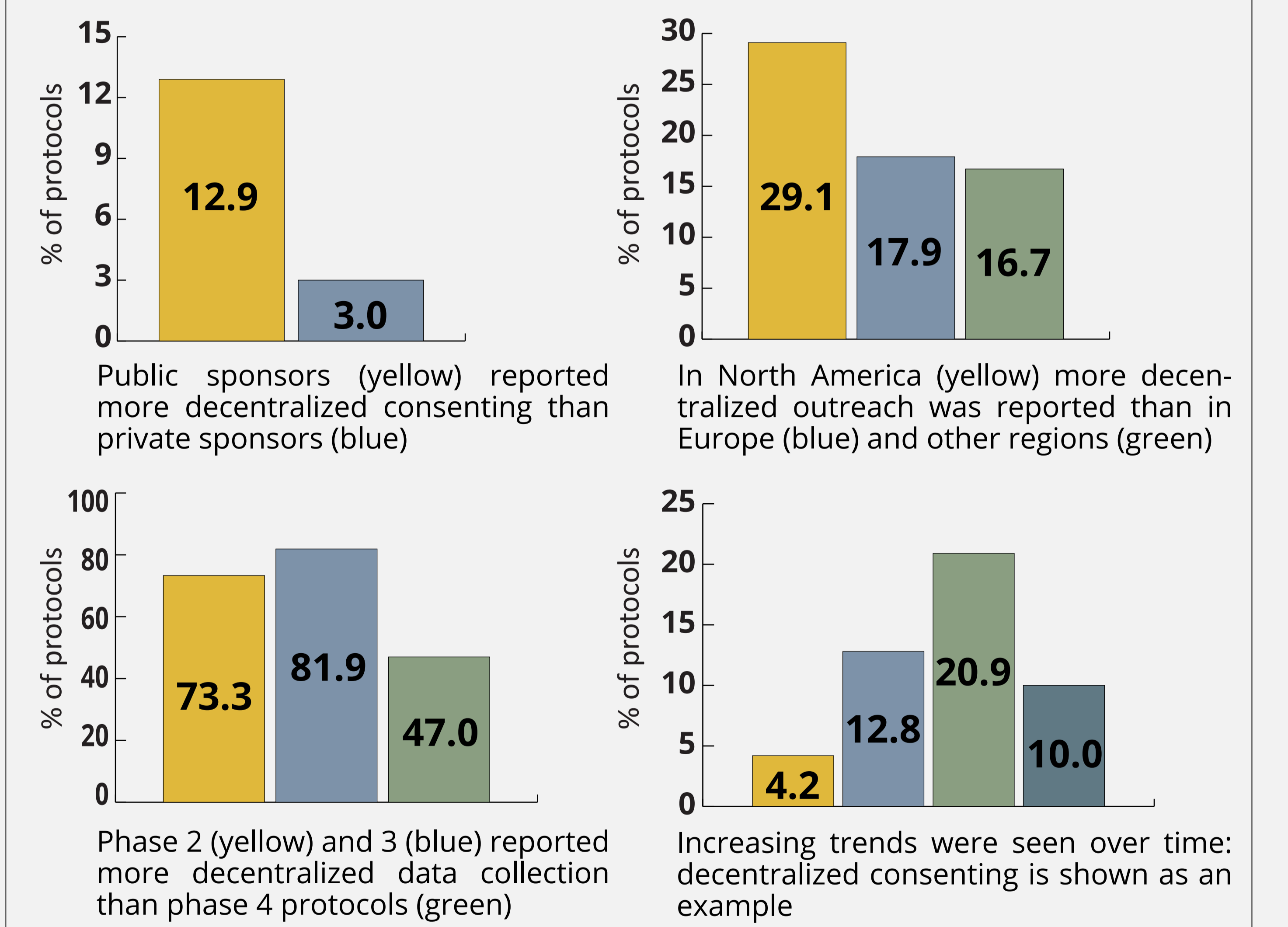
RESEARCH HIGHLIGHTS



RESULTS



Sub-group analyses



CONCLUSIONS

Decentralized trial activities have been included in publicly available trial protocols, although on-site activities were reported more often for all investigated trial activities. Of the decentralized trial activities, decentralized data collection is used most commonly in clinical trials. Decentralized trial elements are more frequently reported in protocols from 2020, possibly due to COVID-19. Sharing best practices can now progress future use of decentralized trial activities to benefit trial participants.