

Decentralized Trial Elements Reported in Publicly Available Clinical Trial Protocols

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INTRODUCTION

The majority of clinical trial (CT) activities is conducted in-person at investigative sites, but bottlenecks have been associated with traditional CT conduct⁴.

Decentralized CT elements (i.e., operational trial activities taking place outside the investigative site) could reduce these issues⁵.

Opportunities of decentralized elements



GOAL

To quantify the reporting of decentralized elements in phase 2, 3 and 4 interventional CT protocols in a cohort of studies with study start date in 2019 and 2020.

METHOD

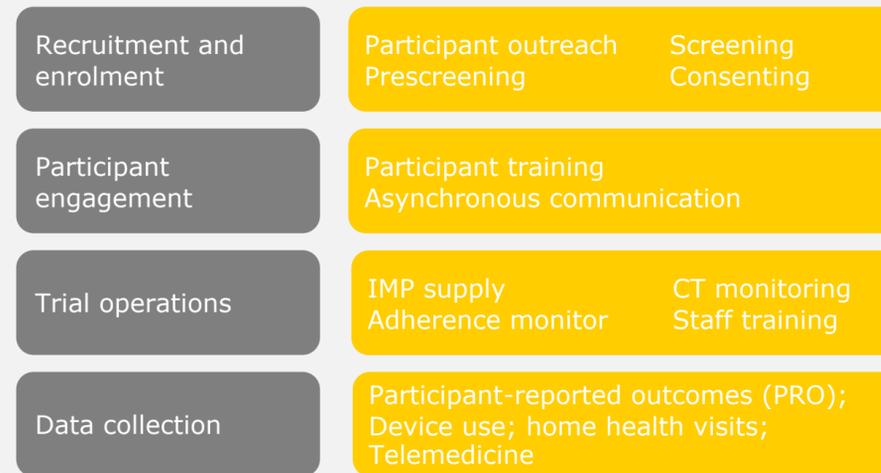
Publicly available protocols from phase 2, 3, 4 interventional clinical trials with start date in 2019 and 2020 downloaded from ClinicalTrials.gov.

Manual extraction of reporting of CT elements using a coding matrix.



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Figure 1. Coding matrix with predefined trial activities



RESULTS

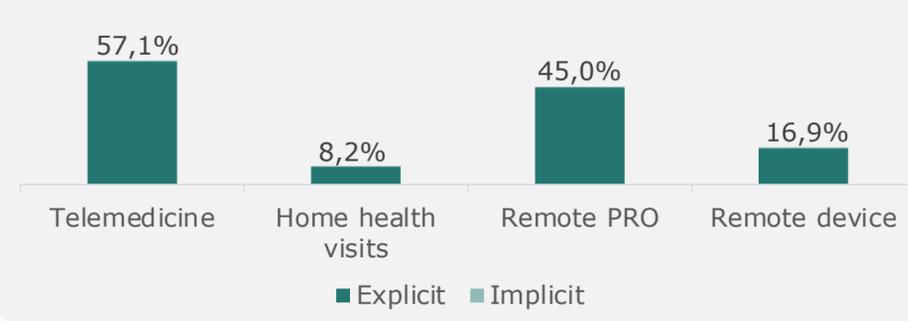
254 eligible protocols included:

- 75% had a (planned) trial start date in 2019;
- 46% of phase 2 studies, 28% phase 3, 26% phase 4;
- 39% had a private sponsor and 61% a public sponsor.

Decentralized conduct of all predefined trial activities were infrequently found, except remote data collection (reported in 68.9% of the protocols). Distribution of different remote data collection methods shown in Figure 2.

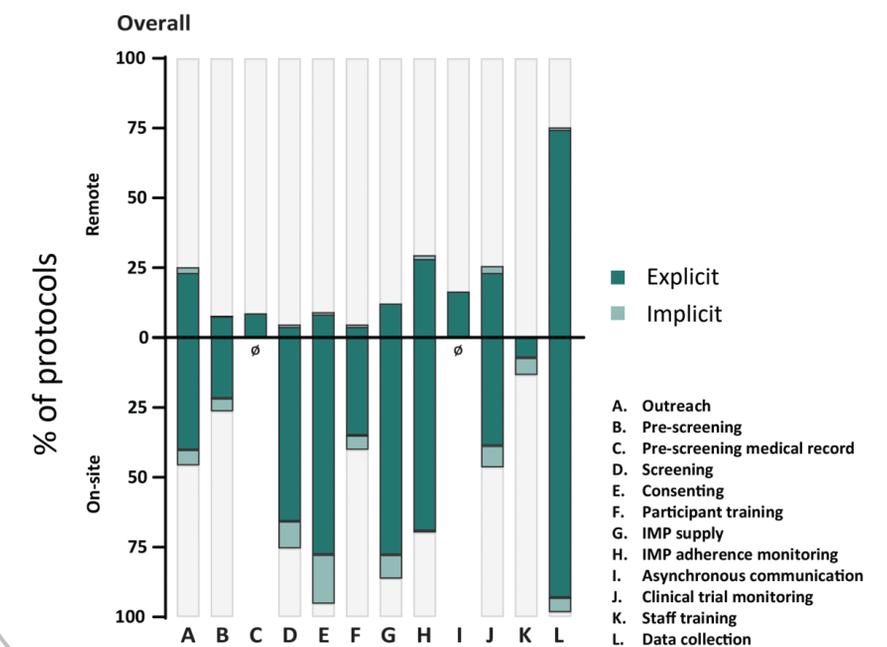
The majority of protocols described combinations of decentralized and on-site trial elements, see Figure 3.

Figure 2. Distribution of remote data collection methods



- Marginal differences between 2019 and 2020 protocols, except IMP supply (8.3% in 2019; 26.7% in 2020) and remote consenting (1.0% in 2019; 17.5% 2020);
- Public sponsors reported more remote outreach (30.3% versus 17.1%), consenting (12.9% versus 3.0%), IMP supply (15.0% versus 8.5%), and async. communication (19.4% versus 12.1%); private sponsors reported more remote CT monitoring (49.5% versus 10.3%) and remote data collection (93.8% versus 61.9%).
- Marginal differences between study phases.

Figure 3. Reporting of predefined trial elements



CONCLUSION

- Decentralized elements have -albeit infrequently- been included in publicly available trial protocols; remote data collection is most commonly.
- Decentralized trial elements are more frequently reported in protocols from 2020, possibly due to COVID-19.
- In public sponsored trials slightly more decentralized elements were described suggesting a more conservative approach in private sponsored trials.

⁴Review C, Modeling D. Novel Methods and Technologies for 21st-Century Clinical Trials A Review. 2020

⁵Sharma N. Patient centric approach for clinical trials: Current trend and new opportunities. Perspect Clin Res. 2015;6(3):134