



**Insight:** Decentralised Clinical Trials - will they be the future?

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# Executive Summary

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**This report discusses the benefits and negatives of decentralised clinical trials and how we have seen increased growth in them specifically since the pandemic.**

It also raises the question of whether they will become more prominent in the future and what concerns the industry needs to address to ensure that they have the best possible success.



**There are both pros and cons to Decentralised Clinical Trials which have been addressed within this report.**

Decentralised trials can be beneficial with providing patient-generated data as well as reduce overall costs. The issues surrounding clinical trials within this form can vary from guidance still being very new and patient-led data might be inaccurate.



**This report highlights the key takeaways from the recent HealthTechX Summit on Decentralised Clinical Trials**

This was a collaborative event with the primary industry focus on solving a problem that has already occurred. It also raised concerns with health tracking technology from patients and users.



**The report concludes that Decentralised Clinical Trials have the potential to revolutionise the clinical trial process but it is difficult to foresee the exact path they take within the industry.**

Issues are currently being addressed and will hopefully alleviate any concerns and ensure any risks are mitigated in future.



## Introduction

Decentralised clinical trials use digital technologies to collect and analyse patient data via a dispersed network rather than in a centralised clinical environment.

Comparing this strategy to conventional clinical trials could provide a plethora of advantages, including lower costs as they do not require specialist facilities or expensive equipment. They may also be more effective because they can be carried out instantly, reducing the period between data collection and processing.



## The Benefits of Decentralised Clinical Trials

Trials like this can leverage ongoing monitoring of patient-generated data and practical evidence to better understand the effects of a treatment, which has the added benefit of improving data quality. This can give a clearer picture of a treatment's impact, including patient-reported results and actual adherence to prescribed treatment plans. Although they have been increasing in usage for some time, the Covid-19 pandemic really saw the use of them come to fruition due to many trials being stalled.

These can also boost patient involvement and provide individuals with more control over their own care. Patients can readily access information about their treatment and provide data in real-time by employing digital technologies like smartphone apps. Better results and a more satisfying experience for patients may result from this.

# Issues surrounding Decentralised Clinical Trials

Decentralised trials do present certain difficulties as well, such as obtaining regulatory approval and protecting data privacy. For decentralised trials to become more widely accepted and a common way to conduct clinical trials, the industry must address these difficulties. The FDA recently released draft guidance on recommendations for conducting decentralised clinical trials of drugs, biologics and medical devices within the USA.



# Key takeaways from the 2023 HealthTechX Summit on Decentralised Clinical Trials

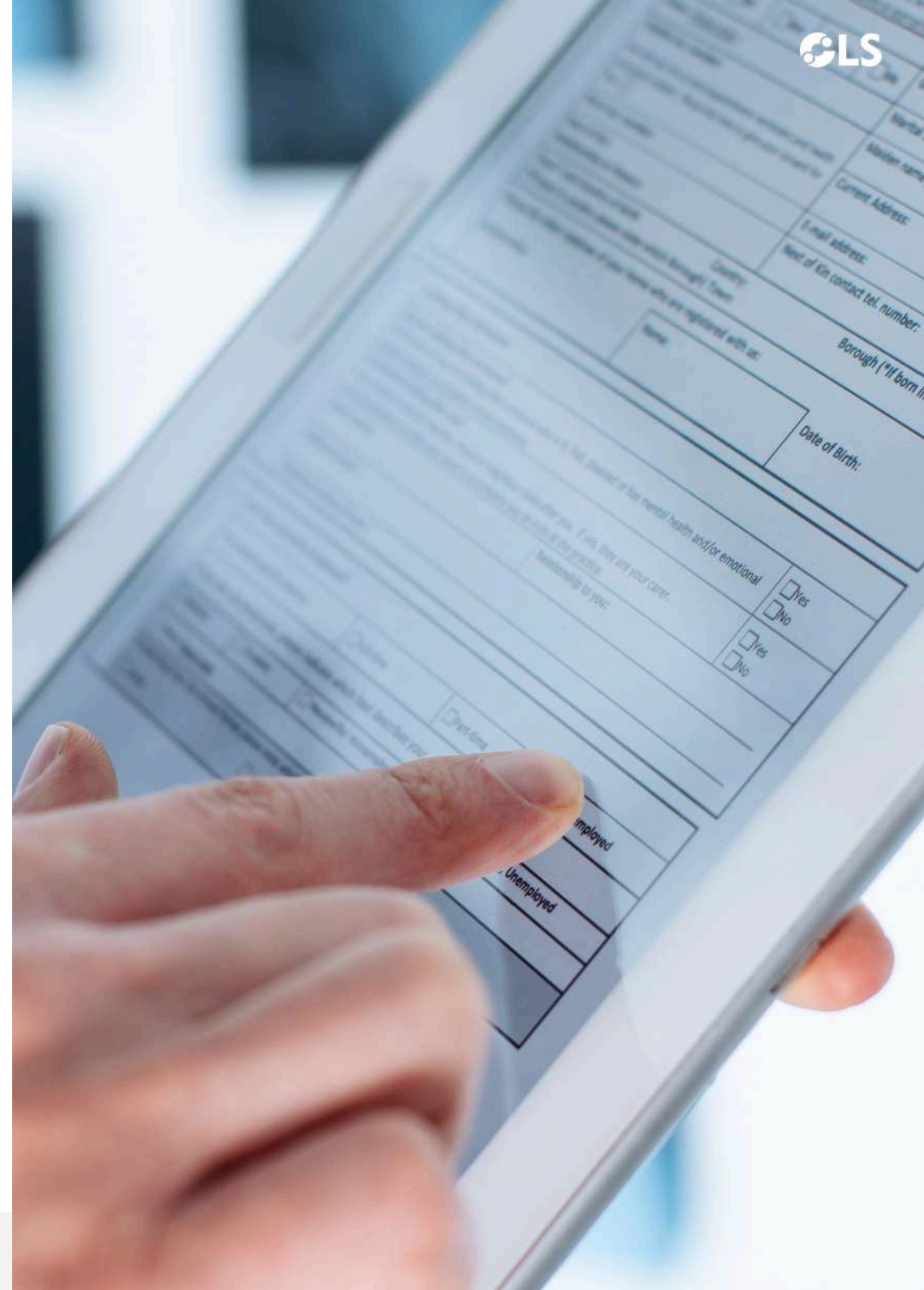
- All efforts appear to be a collective effort to improve patient health
- The biggest part of the industry is finding a solution to a problem that has already occurred - HealthTechX highlighted that technologies like apps and medical devices can be introduced prior to a problem occurring
- Thousands of apps on the market all offering similar things, how does the patient know which is trusted and reliable
- Extensive access to health tracking technology but it all becomes too intrusive and the uptake rate by patients and users is low
- Everyone downloads apps with the best intentions but recording data and using an app does not naturally become a habit
- The event was very collaborative and showed the extent of bringing companies together to work on mutual projects
- The industry working together will come to a solution for patients faster rather than competing and all coming to the same solution too late
- Decentralised trials are becoming the best way to run a trial to cut costs and increase efficiency
- Trial data may be skewed though if patients are recording data themselves

## Conclusion

Overall, decentralised trials have the potential to revolutionise the clinical trial process and result in the creation of novel medicines that are more effective and efficient. To fully realise these advantages and address the difficulties related to decentralised testing, however, will need time and work.

Although it is difficult to foresee the exact course of decentralised trials, it is expected that in the years to come, more clinical trials will make use of decentralised technology. Decentralised trials provide various benefits, including lower costs, more productivity, better data quality, and higher patient involvement. However, there are other issues to be resolved, such as governmental permission and worries about data protection. The European Union addressed some of these concerns by releasing guidelines in 2022.

Decentralised trials will become more and more successful if the sector can overcome these obstacles and win over the confidence of patients, policymakers, and healthcare providers. Decentralised trials have the potential to revolutionise the clinical trial process and result in the creation of novel medicines that are more effective and efficient.





# References

6. Clinical Trials Arena, (2022), *EU regulators publish new recommendations on decentralised trials*, URL: <https://www.clinicaltrialsarena.com/news/eu-regulators-recommendations-decentralised-trials/>
2. Mckinsey.com, (2021), *No place like home? Stepping up the decentralization of clinical trials*, URL: <https://www.mckinsey.com/industries/life-sciences/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials>
1. News Medical Life Sciences, (2022), *Is Decentralization the Future for Clinical Trials?*, URL: <https://www.news-medical.net/life-sciences/Is-Decentralization-the-Future-for-Clinical-Trials.aspx#:~:text=Decentralized%20trials%20have%20numerous%20potential,the%20future%20of%20clinical%20research>
3. PharmTech.com, (2022), *Will Decentralized Clinical Trials Become Mainstream?*, URL <https://www.pharmtech.com/view/will-decentralized-clinical-trials-become-mainstream->
4. US Food & Drug Administration, (2023), *FDA Takes Additional Steps to Advance Decentralized Clinical Trials*, URL: <https://www.fda.gov/news-events/press-announcements/fda-takes-additional-steps-advance-decentralized-clinical-trials>
5. The HealthTechX Summit 2023, (2023), *About HealthTechX*, URL: <https://impactx2050.com/healthtechx/>