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Clinical Trials in the Near Future

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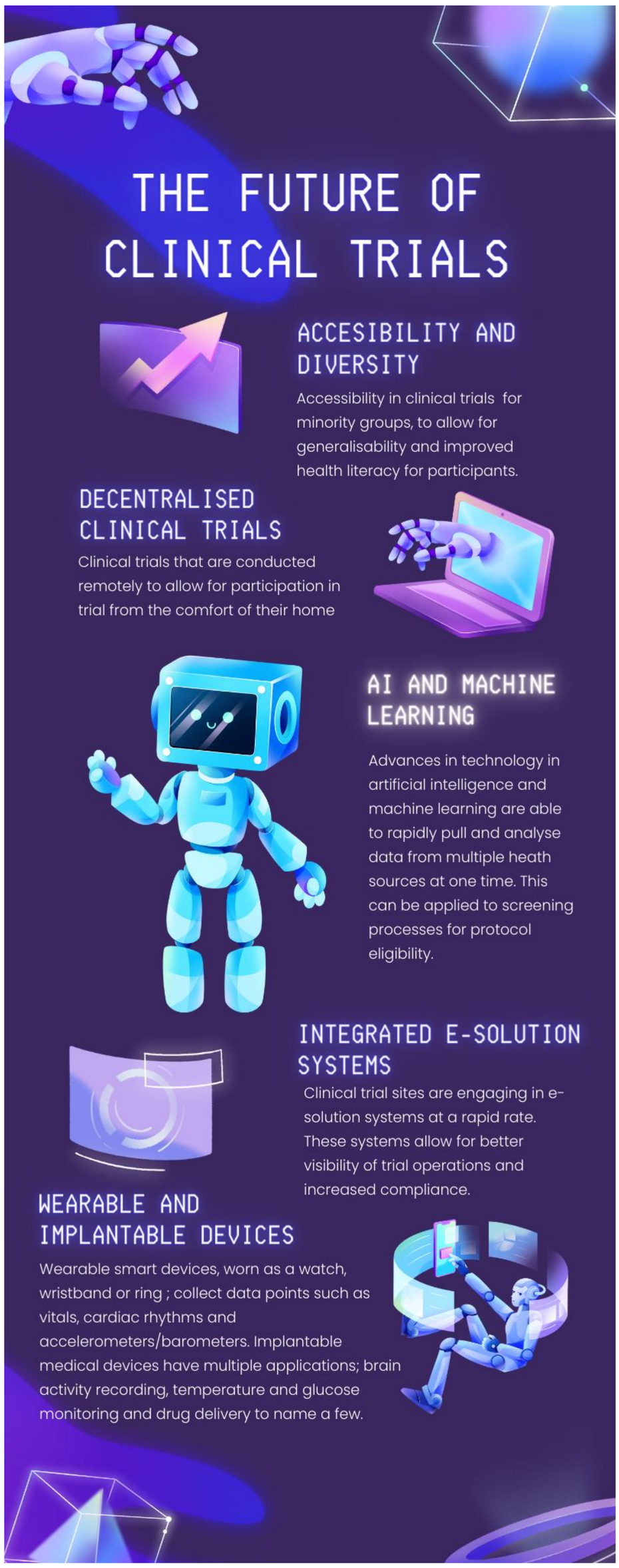
INTRODUCTION

Advances in technology have the ability to change the shape of clinical trials delivery as we know it. Current areas of advances in accessibility and diversity, decentralisation of clinical trials, AI and machine learning, Integrated e-solutions, as well as wearable and implantable devices are areas in which great change may be seen in the near future. This review of the literature is a brief summary of the possibilities that may be available in years to come, if not the very near future.



LITERATURE REVIEW

Accessibility and Diversity

There is a new global focus on including underrepresented populations in investigator and commercial pharmaceutical trials. This is lead by the FDA, and NIH who are driving the importance of including these populations by providing action frameworks and guidance. The increased inclusion of women, Non-English speaking and indigenous populations will allow for more generalisable pharmaceutical translation. These policy changes lead by the FDA and NIH will likely become a commercial requirement, and for Australia to remain competitive in pharmaceutical trials, sites must be able to demonstrate recruitment of diverse populations in trials [1]. Varma et al.(2023) argue that racial and ethnic minorities have less access to quality education and healthcare, and are more likely to have a higher rate of comorbid condition and concomitant medication use [2]. By having less representation of these minority groups can alter the safety profile and can limit understanding of the benefits and risks of the trialed investigational product [2].

Decentralised Clinical Trials (DCTs)

New technologies and IT systems are being developed for clinical trials to be conducted direct to the participant in their own home. The aim of DCTs are to reduce the burden on the participant due to not having to attend clinic visits and improve trial accessibility to minority populations due to geographical distance [3]. As the advancing generations are becoming increasingly tech savvy, the preference may shift to DCTs organically. This may also increase trial participation, not only through geographical motivations but for those with a busy home/life schedule. DCTs are in the infancy stage of development, significant considerations to this model must be around data privacy and security, as our technology advances so must the protection of the data that is collected [4].

AI and Machine Learning

Artificial Intelligence (AI) are computers and robots have the ability of behaving to mimic and go beyond human capabilities [5].
Machine Learning (ML) a subset of AI uses algorithms to automatically learn and recognise patterns from the data to allow for better decision making [5].
AI and ML have the ability to identify new target discovery and toxicology prediction, predict patient outcomes in clinical trials, predict probability of trial success, provide more accurate hypothesis, enhance trial participant selection, have closer monitoring and compliance of investigational product, improved imaging review, analysis improvements by heterogeneity, input missing data and analysis automation [6].

Integrated e-Solution Systems

Clinical Trials Management Systems (CTMS) are software systems that "manage planning, performance and reporting functions, maintain participant trial information, track deadlines and milestones for streamlined trial management" [7].
CTMS systems reduces the administrative burden on clinical trial sites, increase oversight of clinical trial activity, improve financial management processes and metric analysis [7].
Future advances in CTMSs may move paper CRF and source documentation to automated eCRF systems including direct input to Sponsor eCRFs. These eCRFs may be linked to wearable or implantable devices. Future CTMSs may also have the capability of linking live hospital based data where machine learning and AI can occur to better match inclusion exclusion criteria, warning of drug prohibition, warning of absence of visit activity and AE underreporting [8].

Wearable and Implantable Devices

Remote management systems and devices are a modern way of capturing data. Advances in biosensors integrated in wearables such as smartphones, wristbands, rings and implantable devices such as pumps and biochips have the ability to be used for continuous real time drug monitoring , blood pressure, blood sugar, heart rate, pulse rate, ECG, electrolytes, etc. [9,10,11].
Although a promising advance in the delivery of medicine and clinical trial monitoring there is still much to be done to ensure patient safety and accuracy of data. Compliance with wearables, slow upload of data and privacy issues in relation to data security remain a concern. These issues are mirrored with implantable bio sensors with the additional issues of poor accuracy of data and local inflammation due to foreign body response [9].

DISCUSSION

The literature describes a very different landscape to how clinical trials are delivered currently. The importance to remain competitive in the commercial clinical trial setting means that some of these concepts are likely to be translated in the future. AI, machine learning and CTMS systems would have a direct impact on the sites ability to reduce the administrative burden, as well as closer oversight of clinical trials site processes and metrics. The main improvement that will be achieved by these advances appears to be around diversity in clinical trials, this could be possible by decentralisation and AI strategies. Diversity will have a multifactorial improvement not only on the data and the generalisability and translation of research findings but on individualised care of participants. As described by Varma et al (2023) clinical trials participants are more likely to have better health outcomes due to increased health monitoring and improved health literacy compared to non participants. Wearable and Implantable devices look to be promising in terms of the information that could be collected however, ethical considerations should be at the forefront.

CONCLUSION

This literature review was a brief snapshot of the possibilities of future clinical trials. Although many of these advances are currently unproven and mostly theoretical, as technology and data security improves, these factors may become a reality. This would enable the identification, delivery and management of a more diverse clinical trial population.

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