Virtual clinical trials in vogue

Studies conducted without patients visiting clinical trial sites are catching on fast in the pandemic season

Virtual/digital clinical trials – performed by partly or entirely avoiding patient visits to clinical trial sites – have become the new flavour of the season in the post-pandemic setting. Virtual trials using digital technologies to facilitate patient-related activities are also called patient-centered trials. During the pandemic, more than 1,000 clinical trials were suspended as patients could not visit the hospitals. The industry and the investigators considered alternative digital approaches to facilitate patient participation in clinical trials.

Home-based or direct-to-participant clinical trials offer many potential benefits to patients. They can participate in trials from anywhere at any time and do not have to visit the trial sites. The patients can save time and cost of travel and food, and avoid indoor admission. This is of immense value to patients with physical handicaps or cognitive function limitations and their caregiver family members. Clinical trial sites can recruit more patients as they have access to a wider population without the limitations of geographical location. There is likely to be a reduction in the cost of space and staff as well.

The successful conduct of virtual, patient-centered clinical trials requires the following: 1) a central clinical trial coordination centre overseen by the investigator team to organize all clinical trial activities, 2) participant contact with the site by phone, email, or video, 3) the selection of patients from hospital records, health camps, or social media, 4) an electronic consent process 5) a telemedicine interview or examination for clinical assessments supported by limited examinations at the home by the research staff, 6) portable in-home tests e.g., oximetry, spirometry, 8) imaging, e.g. MRI, at a facility near patient's home, 7) home collection of lab parameters by a central lab, 8) the shipping of treatment at home, 9) the administration of parenteral treatments at home by research nurses, 10) participants reporting adverse events to the centre by telephone, the study website, text messages, or email, 11) medical care for adverse events at local medical facilities, and 12) patient data entered by patients or collected by mobile devices and wearable sensors.

For planning virtual clinical trials, several challenging issues must be considered.

Phase 3 clinical trials, pivotal in the assessment of risks and benefits and new drug approval by health authorities, include measurement of complex efficacy endpoints and the administration of potentially toxic new drugs under medical supervision at clinical trial sites. The storage of these drugs may require special conditions which would not be feasible at the participant's home. Hence, phase 3 trials cannot be conducted virtually. But digital conduct of phase 4, post-marketing trials of approved drugs may be feasible.

Home-based trials require the patients to be familiar with the use of mobile devices, internet access, computers, tablets, and/or video-enabled devices for telemedicine. This would be a major obstacle for the elderly and those with physical or cognitive difficulties. In India, limited access to the internet and the difficulty of providing home-based medical care amongst the lower socio-economic strata would be a significant barrier in implementation.

Finally, a careful consideration of the impact of the digital approach on the quality, integrity, and validity of clinical trials would be critical before its widespread adoption. ◪

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