The evolution of clinical trials in response to COVID-19

To the Editor: The clinical trial landscape has arguably progressed more in the past 6 months than in the previous 10 years. The needs of humanity in the global pandemic catalysed the necessity to evaluate study design, implementation, governance, technology and collaboration. The race for effective therapies and a vaccine highlighted the need to expedite drug development and approval. While clinical trials in oncology have used master protocols for many years, with clear guidance from regulatory authorities[1] and a gradual adoption in other therapeutic areas,[2] these have become the blueprint for coronavirus disease 2019 (COVID-19) clinical trials developed by the World Health Organization, ensuring the ability to test a broad range of therapies.

COVID-19 has also triggered the adoption of technology to support trials, accelerating the move to a digital age of clinical trials.[3] Platforms to deliver online recruitment, electronic consent, wearable devices, artificial intelligence and electronic systems for source data and regulatory documents now provide the solution to maintaining clinical trials activity, at a time when restrictions challenge the viability of face to face trial operations. The need for comprehensive, integrated electronic medical records is evident, with enduring access for parties for data verification, but raises issues of access, privacy and cybersecurity.

Out of necessity, clinical trials have also adopted teletrials, like the need in medical practices to adopt telemedicine,[4] resulting in a dispersed, decentralised model of operation. The pressure to adapt clinical trial delivery has seen previously perceived barriers fall away. By focusing on common goals, collaboration, technology, and building solid foundations to evaluate our progress to ensure research integrity and safety, a new era of clinical trials will unfold. The clinical trials team of the future will evolve, incorporating a core team with information and communication technology capabilities to support training, management and development of trial systems in a networked model of delivery. While this is a welcome push into a new technological era, with an opportunity to retain new elements and abandon outdated models, we must proceed with thoughtful consideration and evaluation of our progress.

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