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Going Digital Transformation of Oncology Clinical Research

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Description

The COVID 19 pandemic pushed the oncology clinical research to an in-depth reengineering process. The article published at Contemporary Clinical Trials Communications [1], being part of the global literature of the World Health Organization (WHO) [2], Recommends several strategies to reduce and mitigate the risks in conducting oncology clinical research during the pandemic. Several actions led to decreased patient enrollment, and operational adjustments to comply with patient safety significantly affected the already lengthy study timelines. As a result, stakeholders are adopting technology-based approaches to reduce in-person patient visits to minimize COVID-19 dissemination and remote data monitoring.

Telemedicine connects the convenience of the internet and ready accessibility of health information. Social distancing using traditional phone or video conferences was essential to the most urgent cases. Other authors envision a virtual clinical trial approach where patient visits differ from the clinic or hospital routines, but in the home using sensors and wearables. In 2011, the REMOTE trial (NCT01302938), the first randomized clinical trial under an investigational new drug application, managed study participation entirely using electronic tools, allowing patients to participate in the clinical trial regardless of their proximity to clinical sites. Several approaches permitted distant monitoring 24 h a day, speeding up clinical trials while improving their quality [3]. The efficacy tested in the REMOTE trial was consistent with conventional trial results but might need a simplification and provision of a participant-friendly technology approach, especially for older patients. Several aspects of the virtual trial modality proved operational such as drug delivery, but issues and difficulties such as recruiting participants rendered recalculations [4]. In cancer patients, home infusions are not feasible in terms of infrastructure, and for safety purposes, they are not recommended for drugs with potential for severe toxicities. The virtual trials have revisited and may provide a powerful tool in keeping research participants safer at home whenever possible and eliminating any non-critical hospital visits.

Digital clinical trials have some key elements: Digital recruitment and retention using social media or electronic consent; digital health data collection with wearables, and sensing technologies; and digital analytics approach based on real-world data, interoperability, artificial intelligence, and precision-guided trials [5]. The use of technology and the internet create a bridge of opportunities with distinct perspectives and risks. A Contract Research Organization (CRO) hack has been discovered when its employees had their data locked out by ransom ware. Clinical trial patients were not at risk, but researchers were forced to track their patients with pen and paper [6].

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A secondary database derived from Clinical Report Forms (CRF) is anonymized and virtually difficult to track patients' identities. However, direct access to the primary database or the medical charts during remote Source Data Verification (SDV) for integrity purposes has created challenges. The current understanding of SDV is now ruled by digital privacy and regulation such as European General Data Protection Regulation (GDPR) [7]. Remote monitoring highly increases clinical trial operations efficiency and expedite data locks but needs specific security measures to avoid data breaches in transmission and storage. The mitigation of the risks shall involve all stakeholders. It is noteworthy; Data bleach may occur independently of digital technologies such as patient picture dissemination or unconsented copies of health information documents.

To research sites, the digitalization imposes a tremendous challenge. Remote data access requires investments in security systems to permit monitors and auditors to check data remotely in the research site's primary database. This implicates the necessity of interoperability of the systems if digital. It is not uncommon for research sites to use paper-based documentation. To mitigate breach risks, block chain and separate databases may improve security. On the other hand, research site staff should be prepared and educated for digital transformation. The culture change would transform each member into a good practice guardian for virtual data management. The comprehension of risks and their potential negative consequences is crucial to build a controlling mindset without limiting research activities.

Conclusion

Although the development of systems or acquisition of a third party vendor platform would be required for digital clinical trials, the focus on the research staff would be the main point to sustain operations. Computer scientist's background and site coordinators with engineer's mindset would be highly desirable in data management. The language and communication would change to incorporate data security and cloud concepts, and the ethics reconceptualization shall discuss digital approaches for patient identification other than the name, date of birth, or finger prints. From this perspective, clinical trial specialists' education should change as to cover the conceptualization of digital world. For the next years, patient engagement, processes, project management, logistics, and many other aspects that won't be necessarily in-person or through face to face meeting would design new study protocols and conduction.

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