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Global provider of eCOA and patient-centric solutions

Clinical trials digitalization: why it helps clinical trials stakeholders

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The decline in R&D ef?ciency is one of the biggest challenges the pharmaceutical industry is facing today. The development of complex new therapies targeting smaller patient populations in a timely manner and in a competitive environment requires huge investment. As a consequence, clinical trials are changing, and their evolution to digital, although accelerated by the pandemic, must still undergo considerable transformation in order to face these challenges. If well planned and implemented, clinical trials digitalization will be beneficial to patients, sites, and the industry.

4 drivers for increasing the use of digital technologies in clinical trials:

#1 Inability to recruit or retain subjects: In a survey carried out by the Center for Information and Study on Clinical Research Participation (CISCRP)[1], 'study location' and 'visits too time consuming' were cited by 23% and 11% clinical study participants, respectively, as their least favorite aspect of their experience. When considering participation in a clinical study, the most important information for patients includes the potential risks and benefits (83%), but more practical aspects follow closely such as the medical procedures required and physical location of the site, suggesting that the trial burden will be a barrier to patient enrollment.

#2 Decrease in trials efficiency: despite an increase of 9% in the total number of clinical trials in 2018 over the prior year (and 35% over the past five years), the success rate of clinical development from Phase I trials to regulatory submission fell to 11.4% in 2018 (down from 14.4% in 2017), and was below the average of 14% in the prior ten years[2].

#3 **Spiraling costs vs flat number of new marketed drugs:** The pharmaceutical industry spent over four times more on research and development in 2015 than in 1995, with no corresponding increase in the number of drugs approved by the FDA.

#4 **Facing unforeseen crises:** global crises such as the COVID-19 pandemic can severely restrict movement of people, accelerating the need to develop adapted remote technologies to allow clinical trials activities to continue.

Digital solutions are changing the way industry handles and manages clinical data

The emergence of digital tools having the ability to directly handle vast quantities of data are transforming the use we make of the physiological and biological signal.

Biological and physiological data captured by connected devices directly provide the key essence that makes the clinical trial successful. Not having to rely on heavy site logistics and a large number of systems, nor going through the challenges and costs linked to data verification, data cleaning, and data transfer activities will be a game-changer in the very near future.

Combining data from multiple sensors and devices with eCOA technology can create a large, complex data set that is beyond the current capacity of standard electronic data capture systems (EDCs). Data will now feed in from wearables and mobile devices, eCOA systems, mobile research nursing, televisits, local labs, and EDCs.

In an ICON survey on 'Improving Pharma R&D', the Big Data, AI/Predictive Analytics and mhealth' were cited by respondents as "*the disruptive technology trends which will have the greatest impact on clinical trial operations*"[3]

Electronic data collection and clinical trials decentralization enable patient-centric trial designs

Digital solutions such as eCOA, connected devices, and wearables have gradually gained adoption in clinical trials to track patient outcomes. The use of ECG devices for the measurement of cardiac effects of drugs and to detect cardiac toxicity is well-established, but the past 3 to 4 years have seen a significant increase in the use of other connected devices such as the instant measurement of blood glucose, physical activity, or pulmonary function.

The use of televisits and additional services such as mobile nursing or investigational drug shipments direct to patients are also becoming more common, and are strong facilitators of decentralized clinical trials, which will tremendously reduce the burden for patients.

- Decreasing the visit burden: totally site-less trials or reduced on-site visit schedules will grow with direct data collection and telemedicine-related services; patients are able to remain in their own home while their biometric, ePRO or eDiary data are transferred, reducing or eliminating the need for patients to travel to a study site. When site visits remain needed due to study procedures that necessitate specific equipment or therapy administration, the use of digital technology has the potential to reduce the length of the site visit. This is helpful for many patients who may live either in remote areas, or with impaired quality of life such as severely ill cancer patients, or fragile populations such as elderly or pediatric populations.
- Connected devices will facilitate data provision via direct data streams: discrete and continuous data can be easily captured and quickly transmitted via integrated systems, reducing the demand for patients. Although the percentage of trials using connected medical devices remains low (8%), it has doubled since 2016 and continues to rise[4].
- Increasing the use of eCOA and e-diaries in clinical trials, even for primary endpoint measures, will make it easier for patients to provide data and complete their questionnaires/diaries in their own time in a user-friendly fashion.

Electronic data collection and monitoring will streamline sites' operating processes

The digital solutions implemented in clinical trials will not only reduce the burden for patients but will also have a positive impact at the clinical sites, as long as they are well planned and implemented.

- Integrating data capture and transfer, and potentially using integrated systems, will allow the technical and procedural burden at the site level to be reduced. Also, some of the numerous activities dedicated to the set-up and maintenance of multiple systems at a study site will be managed by the devices and e-data collection manufacturers.
- The current burden of monitoring, not only for sponsors and CROs but also for site staff, is alleviated with the remote monitoring, risk-based monitoring (RBM) and direct clinical data review and reconciliation that are facilitated by electronic solutions.
- Real time monitoring of patient compliance allows for targeted actions to be implemented by site staff in a timely manner
- A shift to hybrid or decentralized trials will decrease the number of visits and/or the time spent on site, which will free up time that site staff will be able to allocate to other activities.

However, the shift to hybrid trials will affect sites staff who will need to invest time in training for proper technology adoption, and who will have to adapt their infrastructure to face the growing digital demand.

The industry is still paving the way towards the digital transformation of clinical trials. Embracing the digital evolution means much more than investing in and implementing new tools and systems: a greater degree of sophistication is required. The successful roll-out of the new generation clinical trial requires new expectations to be well understood and the skillset of both the study teams and the site staff to shift. Clinical science in the 21st century will require a flexible operational model and experienced study teams that understand patient needs, listen to site requirements, and have expertise in electronic device logistics and handling.

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See “how can digital innovation turn clinical trials into a positive patient and site experience”:

Learn more

References

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