Accelerating adoption of decentralized trials in a post COVID-19 era

www.hexaware.com

Table of Contents

Foreword

The impact of the COVID-19 pandemic on the operations of clinical trials across the globe is grave. Pharma and clinical research companies are trying to mitigate the challenges. The operations in the clinical trial space have stalled due to the fear of cross-infection. The healthcare industry has a two-pronged strategy to mitigate the effects of the pandemic a) assessment of the current situation b) the optimal way forward.

90% of clinical trials worldwide have halted enrollments for trials, impacting them at their early stages. The lack of early-stage data hinders continued drug development in Phase 3, causing delays in the entire drug development lifecycle. The anxiety of cross-infection has made patients withdraw from trials and virtually it is difficult to track medication adherence. To ensure protocol adherence for seamless virtual trials and patient engagement in these unprecedented times, organizations are adopting technological interventions for faster recruitment of patients, ensuring their adherence to medication and retaining them successfully by providing them support through digital means.

This white paper explores and examines the paradigm shifts taking place in the clinical trial sphere and how organizations are accepting the technological interventions. This paper also reinforces the urgent need to enable virtual clinical trials to help organizations adapt to the current scenario.

Current Scenario

CROs and Pharma are currently engaged at an unparalleled speed in supporting COVID-19 rescue studies and operationalizing non-COVID-19 studies in a remote setting. Following is a table charting out the basic differences between traditional and virtual trials:

Parameters	Traditional Trials	Virtual Trials
Study operations	Centralized Clinical Research Center	Virtual site connected remotely
Site	Multiple locations with investigators and diagnostic facilities	Multiple virtual locations connected online with lab, investigators & subjects
Subject	Personal assessment	No human interaction with patients
Clinical Data	Data collected locally in EDC/ paper CRF	Remote data collection

Clinical trials have faced extensive disruptions due to social distancing measures and travel restrictions across the world. At the expense of other health indications, organizations are shifting their research and development (R&D) priorities towards finding vaccines and new treatment regimens for COVID-19. This situation has propelled an accelerated adoption of technologies like telemedicine, virtual trials, and electronic data management to ensure connectivity of patients with investigators and providers and maintain R&D continuity in such uncertain times. An analysis of data reveals that almost 3%-4%[i] of global clinical trials have been affected due to the pandemic. However, given the huge impact of the pandemic of the clinical trials sphere, this provides an underestimate, as patient dropouts and trial postponements continue. The per-day delay in clinical trials causes revenue loss of approximately $8 million[ii]. The situation still looks grim as trials continue to be suspended temporarily or permanently, but COVID -19 is making organizations adopt technologies to ensure resilient clinical trials.

Impact of The Pandemic

88% of global pharmaceutical companies and CROs are investing in remote trial monitoring solutions

Enterprise contact center call volumes are jumping over **800%** from normal levels during COVID-19 trials

Globally, there is a **~30%** drop in new subject enrollment, resulting in an **800%** hike in caseloads recently

Clinical trials are getting hard hit at the early stages. 90%[iii] of clinical trials have close enrollments worldwide; over 66%[iv] of COVID–19 affected industry-sponsored trials are in Phase 1, 2 or in development. The lack of early-phase data hinders continued development in Phase 3 trials, thereby delaying processes of drug approval, clinical and commercial plans. Therapeutic areas like oncology, autoimmune disorders, cardiovascular disorders are facing the most impact as delays prevent patients from getting access to life-saving medications. At present, more focus is being aligned towards COVID-19 rescue studies rather than non–COVID-19 studies. Increased patient anxiety and hesitance to visit trial sites due to fear of infection is also compelling organizations to halt trials indefinitely.

To mitigate the issues in the current scenario, CROs are shifting their priorities

Virtual is set to become the norm in clinical trials and real-world studies. The market size for virtual clinical trials is set to grow at a CAGR of 5.1%[v] from 2020 to 2027 with COVID–19 expediting the process at an unprecedented speed

55% of life science professionals believe a quarter of all trials will be conducted virtually within one year

There is need for reassessing and understanding the new patient journey in a virtual set-up

Optimization of study operations is critical to the management of protocol deviations

Enhancing support to offerings built to engage patients remotely

Patient support through Contact Centers is scaling at an extraordinary pace while reimagining the future of customer service

Customer support development to mobile health that addresses patient adherence and engagement

Navigating Through the Changing Priorities

Over time, there has been a transition and significant developments in the clinical trial sphere:

Fostering patient centricity in clinical trials

Patients today have more knowledge about health and wish to be more involved in their health-related decisions. This transition can be attributed to access to the internet for them to be educated. Hence, patients are no longer mere subjects in a clinical trial but active collaborators. To foster this practice, pharmaceutical companies are researching new and innovative ways to engage and educate patients.

Data sharing

Since patients are more actively involved in trials, there has been an increase in transparency in the entire clinical trial lifecycle. This increasing focus on transparency has led to making data more available and open. This brings in the question of data security. Organizations are adapting themselves to the requirements provided by the regulatory authorities to transform in the transparent environment.

mHealth and Wearables

Data collection through wearables is gaining momentum. These are serving as key mechanisms to collect, track and solicit patient data virtually and remotely. This is serving as a bridge to the barrier of social distancing and access to clinical trial sites by patients due to the COVID-19 pandemic.

Increased focus on cyber-security

Attacks on vulnerable clinical trial data can prove detrimental to both finances and reputations of organizations conducting trials. Innovative blockchain solutions can help encrypt data, break silos and improve overall collaboration between the stakeholders of a clinical trial, thereby providing secure data handling.

Driving better patient engagement

For driving better engagement in the virtual scenario, the new trend is to offer a single view patient portal for maximized engagement and using it as a scalable information center across the entire patient journey. Such portals are also delivering personalized messages specific to medication or disease state to engage and educate patients, send reminders and check on progress throughout the day. AI for predictive analytics is also being used to identify patients who will most likely stop the following medication and suggest methods of intervention.

Delivering value beyond therapeutics

Services that go over and beyond therapeutics offerings help accelerate revenues. CROs are now delivering value beyond pills while continuing to strengthen patient relationships. Reports suggest that less than half of patients (47%)[vi] said pharma companies understood their emotional, financial and other needs related to their condition. Offering value-added services and personalized care and support gives the edge for CROs to win against this perception.

Challenges While Conducting Clinical Trials

Ensuring protocol adherence and seamless patient engagement

Extending digital patient support in a virtual clinical trial setting

Ensuring protocol adherence from start to finish can be quite challenging. There are serious consequences of dropouts – from costly delays to missing data that can compromise the results and integrity of a study. Following are some of the issues from an enablement perspective:

Access to Sites

COVID-19 has made most of the sites inaccessible. Traveling to sites could be detrimental if exposed to COVID-19. Hence, virtual trials and remote monitoring of patients has gained precedence.

Protocol Adherence

Supporting patients with adherence and treatment continuity and adapting the clinical trials' protocol to mitigate the impact of COVID-19 has become crucial.

Patient Retention

Lack of comprehensive patient data leads to inefficient case management and poor patient retention.

Fragmented Systems of Collaboration

Dealing with multiple systems and stakeholders during the trials impacts patient experience significantly.

As organizations are working towards delivering digital patient support, a cognitive contact center is critical to managing this shift for patients and sponsors. Hence, it is imperative for organizations to resolve the issues as follows:

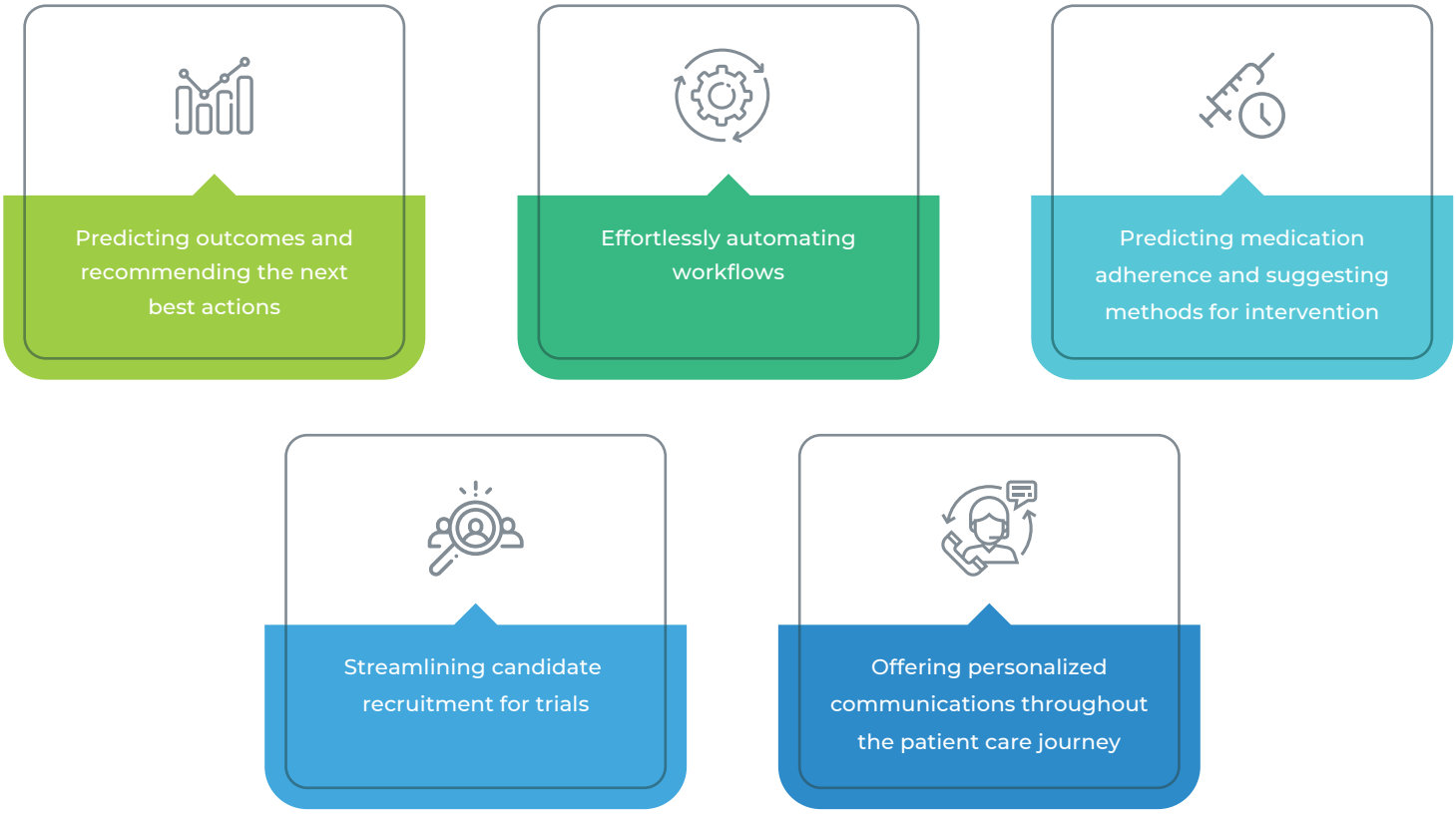
- Ramping up 'superior' capabilities in a remote or risk-free setting
- Offering flexibility in support across multiple languages while ensuring technology readiness
- Standardizing operations with best-in-class technology
- Offering compassionate-cognitive interactive experiences
- Bringing efficiencies via transformation

Technological Adoptions for Expediting Clinical Trials Post COVID-19

COVID-19 has made it imperative to shift to digital patient engagement to support clinical trials. Organizations are now leveraging digital capabilities like telemedicine to ensure continuity of trials. Currently, 60%[vii] of major pharmaceutical companies are using telemedicine for trial visits.

Digital health technologies are being extensively used to collect vital data from patients at home. Wearables and sensors are being used to gather patient data on their biometrics and functionality such as heart rate, sleep details, glucose monitoring and sweat analysis, thus capturing the effects of a medication or illness every day. Digital health technologies are also being leveraged for preventive monitoring. Any deviations from normal in the data recorded remotely may trigger an alert to the trial team to offer better care and escalate the case as per priority. An example of the same can be a contact center agent calling a patient to check on his/her health status based on the alert triggered, as the patient had a severe drop in blood pressure during the specific day.

CROs are increasingly leveraging Cloud and AI technologies to increase operational efficiency and deliver actionable insights across R&D and commercial operations. AI helps in



The Way Forward to Accelerate & Scale Digital Clinical Trial Journey

Organizations can leverage the following digital enablers for accelerating their digital clinical trial journey:

Digital Enablers	Impact
AI-enabled trial matching	Faster recruitment in virtual clinical trials
Digital Pre-screening	
eConsent	
Patient Portal	Accelerated patient engagement enabling study team collaboration remotely to look at patient health during the trial and also monitoring adverse events, if any
Telemedicine	
Remote Monitoring	
Cognitive Contact Center Support	Improved patient retention in trials and effective tracking of protocol adherence

References

[i] COVID-19 and the impact on the clinical trial space;
https://pharmaintelligence.informa.com/~/media/informa-shop-window/pharma/2020/files/whitepapers/covid-19-and-the-impact-on-the-clinical-trial-landscape.pdf

[ii] Hargreaves, B. Clinical trials and their patients: The rising costs and how to stem the loss. Pharmafile. (Online) Available at:
http://www.pharmafile.com/news/511225/clinical-trials-and-their-patients-rising-costs-and-how-stem-loss

[iii] Conduct of Clinical Trials in the Era of COVID-19: JACC Scientific Expert Panel
https://www.sciencedirect.com/science/article/pii/S073510972037234X

[iv] COVID-19 and the impact on the clinical trial space;
https://pharmaintelligence.informa.com/~/media/informa-shop-window/pharma/2020/files/whitepapers/covid-19-and-the-impact-on-the-clinical-trial-landscape.pdf

[v] Virtual Clinical Trials Market Size, Share & Trends Analysis Report By Study Design (Interventional, Observational, Expanded Access), By Indication (Oncology, Cardiovascular), By Region, And Segment Forecasts 2020 – 2027
https://www.grandviewresearch.com/industry-analysis/virtual-clinical-trials-market

[vi] 5 trends impacting clinical trials in 2020
https://www.solvedge.com/Clinical-trial.html

[vii] Post pandemic clinical trial strategies: How COVID-19 altered clinical trials forever and what's next
https://www.iconplc.com/insights/blog/2020/08/05/post-pandemic-clinical-tr/index.xml

About Hexaware

Hexaware is the fastest growing next-generation provider of IT, BPO and Consulting services. Our focus lies on taking a leadership position in helping our clients attain customer intimacy as their competitive advantage. Our digital offerings have helped our clients achieve operational excellence and customer delight. We are now on a journey of metamorphosing the experiences of our customer's customers by leveraging our industry-leading delivery and execution model, built around the strategy - 'Automate Everything™, Cloudify Everything™, Transform Customer Experiences™.' Hexaware services customers in over two dozen languages, from every major time zone and every major regulatory zone. Our goal is to be the first IT services company in the world to have a 50% digital workforce.

Learn more about Hexaware at **www.hexaware.com**

NA Headquarters
Metro 101, Suite 600,101
Wood Avenue South, Iselin,
New Jersey - 08830
Tel: +001-609-409-6950
Fax: +001-609-409-6910

India Headquarters
152, Sector – 3
Millennium Business Park
'A' Block, TTC Industrial Area
Mahape, Navi Mumbai – 400 710
Tel : +91-22-67919595
Fax : +91-22-67919500

EU Headquarters
Level 19, 40 Bank Street,
Canary Wharf,
London - E14 5NR
Tel: +44-020-77154100
Fax: +44-020-77154101

APAC Headquarters
#09-01, One Finlayson
Green, 1 Finlayson Green,
Singapore - 049246
Tel : +65-63253020
Fax : +65-6222728

Australia Headquarters
Level 3, 80 Mount St
North Sydney NSW 2060
Australia
Tel : +61 2 9089 8959
Fax : +61 2 9089 8989