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Operating a Clinical Trial in the Cloud:

The Fundamental Aspects of Creating an Agile, Scalable and Flexible Solution Capable of Delivering Better Results than Previous Study Models.

Bogged down by recruiting challenges and impaired by inconvenient travel distances, almost half of clinical trial sites miss enrollment targets, with nearly half of patients dropping out before study completion. Because of these issues, clinical trials incur $600K to $8M in potential daily losses.[1] Accordingly, the pharmaceutical industry is quickly pivoting away from "site-centric" to "patient-centric" clinical trials, not only to curb losses but to improve results and outcomes. Through process and technical innovation including remote monitoring, advanced analytics, and agile ways of working, digital alternatives have the potential to help reduce time to market by 500 days and reduce development costs by 25%.[2] More accessible, affordable, and faster than traditional models, digital and decentralised trials can allow for greater clinical diversity, seamless coordination, better trial process control and enhanced patient progress tracking.

When building and deploying platforms to support digital trials, they must be decentralised and focus on connecting patients, Clinical Research Organizations (CRO), and healthcare provider teams through a virtual, user-friendly, outcome-driven experience. Additionally, it must be modular and integrated, following a well-defined capability map and patient end-to-end journey. Underpinning the future of digital clinical trials are these five components: digital enrollment, trial journey/roadmap, omnichannel communications, increased compliance and connected apps. Ideally, an optimal cloud platform should permit life sciences companies to leverage existing technology investments while also helping them integrate best-of-breed capabilities tailored toward their therapeutic area and patient population needs.

Life sciences organisations hoping to improve their clinical trials should find a partner capable of building solutions in the cloud. And the results of switching will have benefits across multiple stakeholders – sponsors, investigators, and patients together with their families and caregivers. Through secure omnichannel communication channels, enterprises can access real-time data to simplify patient recruitment and enrollment. Plus, organisations will enable unified incorporation of patient outcomes, improve operational efficiencies, reduce study timelines and increase patient engagement. Furthermore, these trials will effectively improve enrollment, streamline administrative processes, increase retention, boost patient outcomes and encourage better medication adherence.

Clinical trials are research studies performed in people to evaluate a medical, surgical, or behavioral intervention. It is the primary way that researchers find out if a new treatment, such as a new drug or diet or medical device is safe and effective. Often a clinical trial[3] is used to learn if a new treatment is more effective and/or has less harmful side effects than the standard treatment. While close adherence to process and protocol is a necessary aspect of any testing methodology, the programs, procedures and systems that uphold clinical trials are based on decades old processes and are perceived to lack flexibility and have not yet adapted to current expectations and capabilities based on remote and digital engagement.

The Impact of COVID-19 on Clinical Trials

As society shut down, so too did most clinical trials. Enrollment plummeted[4] and prospective participants noted that they were fearful of visiting hospitals that had become COVID-19 treatment centers. Trials were short-staffed and low on resources as everything got reallocated. Some were too risky to continue, but ones classified as "lifesaving" were kept open. Nevertheless, the SWOG Cancer Research Network reported that enrollment in large clinical trials dropped by half. Small trials – intended to establish new medicine safety – were also paused. Newly launched studies were most impacted by the pandemic – with one study discovering that of 62,000 trials that began before the pandemic, only 57% of the expected number of studies to get initiated came to fruition.

Findings from one very comprehensive study,[3] which analysed data across the globe (but primarily the US), revealed further effects the pandemic had on clinical trials. For example, there was a significant increase in delayed subject enrollment as well as operational gaps in most ongoing clinical trials, which negatively impacted the trials themselves and their data integrity. From a global perspective, outside of the sites overseeing clinical trials relating to COVID-19, all trial sites experienced timeline delays or a total stoppage of operations. More specifically, 69% of the study's respondents indicated that the pandemic affected their ability to perform ongoing trials; 78% believed that the current global crises prevented the initiation of new trials. The study also discovered that (based on the weighted average of their answers) the chief four concerns of staff were patient enrollment, patient recruitment, financial implications from canceled studies and financial implications from delayed milestones. A deeper examination of the issues troubling clinical trials showed that 54.8% of respondents saw a decline in patients' willingness to go to physical sites, but conducting telehealth visits posed a considerable challenge in terms of time restraints. Plus, 51.6% noted concern over the time it took to discuss modifying trial procedures to accommodate patients unwilling to come physically. The same percentage also specified that their limited ancillary services were problematic.

Because of these difficulties, the US Food and Drug Administration created a series of guidelines for clinical trials to follow in order to continue despite the pandemic. The intuition permitted[4] the delivery of experimental medicines to participants' homes instead of having the patient go to the medical center themselves. As online platforms got introduced, people could give consent virtually to participate in clinical trials. The time between doctors' visits got lengthened, doctors made remote visits, and trial staff leveraged phone and video to complete questionnaires. Some participants could visit their local doctor for basic procedures. While these policies got trial enrollment back up to near-normal levels – the longer intervals between assessments meant less data could be collected from patients. And the quality of the trial data decreased as well. Likewise, the efforts to make clinical trials more convenient could not prevent cancer survivors from becoming less likely to enroll in a clinical trial post-recovery. Because of the decrease in clinical trials (particularly for cancer), there is a shortage[4] of tumor samples for even the most

basic research and testing. Recognising that these hybrid solutions were more of a temporary solution, third-party companies worked to consolidate hybrid clinical trials into a more unified experience.

Creating an Integrated, Cloud-Based Platform for Clinical Trials

Bogged down by recruiting challenges and impaired by inconvenient travel distances, almost half of clinical trial sites miss enrollment targets, with nearly half of patients dropping out before study completion. Because of these issues, clinical trials incur $600K to $8M in potential daily losses. Accordingly, the pharmaceutical industry is quickly pivoting away from "site-centric" to "patient-centric" clinical trials, not only to curb losses but to improve results and outcomes. Although switching to a hybrid model served as a suitable substitute, the eventual development of unified, cloud-based digital platforms for clinical trials rectified the lingering questions of data integrity[4] and challenges of conducting telehealth visits.[3] Through process and technical innovation including remote monitoring, advanced analytics, and agile ways of working, digital alternatives have the potential to help reduce time to market by 500 days and reduce development costs by 25%.[2] Likewise, digital trials allowed for greater clinical diversity, seamless coordination, better trial process control and enhanced patient progress tracking. Ideally, when building a cloud-based platform to deliver the future of hybrid and decentralised clinical trials, it must be supported by a virtual, effortless, outcome-driven experience that connects patients, Clinical Research Organizations (CROs), and healthcare providers. Modular and integrated, a digital clinical trial solution expands patient outreach and optimises the study start-up timeline while decreasing the burden on study teams and patients. Moreover, by analysing the exemplar platforms built thus far for the pharmaceutical industry, others can find similar success in this post-pandemic era.

The Five Components Underpinning the Creation of a Clinical Trial in the Cloud

When creating any clinical trial in the cloud, it is foundational to adhere to these five components: digital enrollment, trial journey/roadmap, omnichannel communication, remote monitoring and connected apps.

- Digital Enrollment – The ability to recruit patients from the comfort of their own homes is essential to a digital clinical trial. By equipping CROs, investigators and local HCPs (Healthcare Providers) with tools such as eConsent (Electronic Consent) and TeleConsent, they can remotely screen patients at scale, meet study enrollment targets faster, and accommodate for study needs and patient preferences. And with machine learning and data mining, the enrollment process becomes even more convenient.
- Trial Journey/Roadmap – Keeping the patient engaged is critical, and a roadmap can do just that as it provides the participant with an on-demand overview of their trial progress. Furthermore, an organised journey outfitted with tasks, intelligent reminders, and behavioral nudges will ensure that the patient follows necessary procedures and maintains medication adherence while meeting milestones.
- Omnichannel Communication – The more convenient the clinical trial experience is, the more likely patients will see it through to completion. And by offering secure, mobile and reliable communication channels, patients can schedule visits, contact support or chat with the click of a button. Of course, all telehealth channels must be HIPAA-regulated and encrypted.
- Remote Monitoring – While there must be transparency for the patient via the trial roadmap, the healthcare side also needs a 360 degree view of information for compliance and safety purposes. Through easy-to-pair IoMT (Internet of Medical Things) integration, eCOA (Electronic Clinical Outcome Assessments), ePRO (Electronic Patient-Reported Outcomes) and AE (Adverse Events) reporting and real-time updates, medical teams can guarantee patient safety.
- Connected Apps – To enable faster study start-up timelines and smooth document exchange between sponsor teams and trial site teams, it is vital that a digital clinical trial platform leverage connected apps. Better access and visibility will allow for quicker eCRF verification, query resolution and turnaround times while empowering the seamless exchange of information between all involved parties.

One consideration is that the top digital clinical trial solutions allow clients to leverage existing technology investments, simultaneously helping them build frameworks with best-of-breed capabilities to improve operational efficiencies at sites and increase patient engagement.

Capability Map and The Patient End-to-End Journey

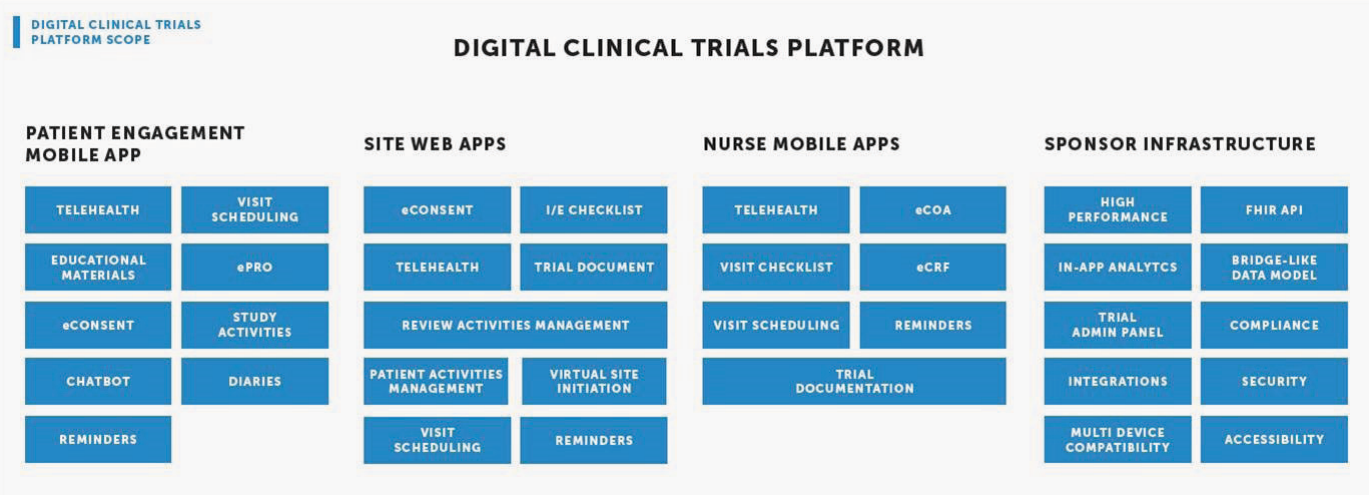
With the five core practices established for the ideal digital clinical trial, it is also noteworthy to closely examine the capability map and patient end-to-end journey implemented within solutions currently available. Capability maps can be split into two sections: the digital clinical trials platform and the data factory. The former divides further into patient engagement on mobile apps, site web apps, mobile nurse apps and sponsored infrastructure. The latter is separated it into analytics, reporting, data ingestion, data lake and IoMT devices. By observing these divisions and segmentations, life sciences companies will glean best practices for their own digital clinical trials.

The patient journey begins with (unsurprisingly) the patient and all the initial interactions the life sciences company would have with that individual. At the outset, the platform will use social media and trial matching to provide visibility of the clinical trial to various patient communities. Once the patient volunteers, the screening and enrollment phase begins. During this time frame, the app uses decision aid features and virtual communication to receive consent from the patient to participate in the trial. The participant will complete a virtual onsite visit as well as an eConsent/screening. Then, the onboarding process, where the patient sets up their profile.

The next phase of the patient journey is the onsite/offsite/patient direct data capture process. This stage is the most involved section and includes the patient completing trial tasks, telehealth visits and surveys. Participants will also get supported by a health chatbot equipped with a symptom tracker which passively captures their data in real-time integrations through connected devices and IoMT. The fourth and final section of the patient journey is the companion stage; the trial participant will receive behavioral nudges to encourage patient retention using alerts, reminders and goals based on health metrics and relevant therapeutic areas. Additionally, to promote re-enrollment, maintain post-trial support and alumni health insights, patients will receive updates and new trial availability based on collected health metrics.

The Benefits of Digital Solutions

As mentioned in the previous sections, a digital clinical trial built in the cloud can benefit all involved parties, including sponsors, investigators and patients. For sponsors, a modular, cloud-based platform can increase recruitment opportunities because it reduces barriers to travel and location via telemedicine so that more eligible patients can enroll from a broader and more diverse area. Sponsors will also benefit from enhanced visibility and enrollment data, that can lead to accelerated study start-up timelines and reduced overall study timelines. Similarly, data and insights from connected



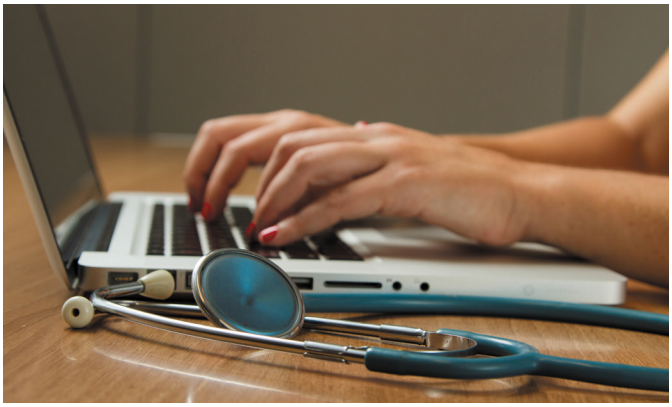
devices can also improve intelligence allowing for richer datasets. Additionally, real-time indicators of patient clinical progress can help sponsors validate digital clinical endpoints for tracking purposes.

Investigators and CROs profit from increased efficiencies that smooth and simplify administrative processes. Moreover, investigators are more likely to see increased patient retention and patient safety from leveraging digital clinical trials as patients are monitored remotely, allowing for early interventions, tailored notifications and round-the-clock support to strengthen engagement and medication adherence. For the instances where patients are immune-compromised, the digital clinical trial can safeguard individuals by minimising their exposure to waiting rooms and/or transportation. Finally, the digitally enabled model provides investigators with a single collection point for internal and partnered platforms, improving protocol structure, streamlining trial execution and enabling more seamless coordination.

As for the patients, it is significantly more convenient than traditional clinical trials since recruitment and trial coordinators come straight to their homes. And regardless of where the patient lives, investigators and HCP can help them through virtual appointments or at-home visits. Now, an even greater clinical diversity is possible, meaning patients of a much greater regional and economic variety can access clinical trials should they volunteer to participate. Plus, patients are more likely to have increased medication adherence enabled by easy-to-use progress trackers, virtual support and early digital interventions.

An Era of Hybridity and Virtualisation

The pandemic has showed that the systems upholding our tightly interconnected world were much more fragile than we hoped. When factories halted in China, the unintended domino effect reached as far as our supermarkets. Nevertheless, we also experienced that the ingenuity and adaptability of people should not be underestimated, as seen in the rapid devolvement and deployment of digital solutions including clinical trials. And although the challenges of data integrity and patient engagement are legitimate, having a dynamic, proactive strategy for risk assessment built into a digital cloud-based solution will ensure that clinical studies not only continue but can actually improve as a consequence. The post-pandemic era values hybridity and virtualisation, from classrooms and offices to concerts and hospital visits. It is likely that many more practices and activities, such as clinical trials, will also convert to digital for convenience, simplicity, and improved outcomes.



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