MARWOOD GROUP

The Virtual Clinical Trial Space: An Industry in Transformation

Executive Summary and Outline

The COVID-19 pandemic has brought virtual clinical trial enablement into focus. A spectrum of technologies transformative to traditional trial management, we present areas of growth in a broadening clinical research vendor landscape flush with investor activity that is rapidly being shaped by regulatory and legislative activity.

I. Introduction

Clinical trials have historically been conducted in traditional brick & mortar trial sites, whether academic medical centers, single sites, site networks, dedicated site groups or integrated physician networks. Virtual clinical trial enablement is not necessarily exclusive of traditional brick & mortar sites, but rather represents a spectrum of potential processes that can be moved away from a set physical location in a hybrid approach (**Figure 1**). In doing so, virtual clinical trials allow for greater throughput, compliance and efficiency in the brick & mortar clinical site model.

While virtual clinical trials were estimated by Marwood[1], immediately prior to the pandemic, to make up a mere 1-3% of all clinical trials, stakeholders at this time nonetheless expected increases in the range of 10-20% YoY over the proceeding 5 years. The pandemic has subsequently brought virtual clinical trial enablement into focus, from both an industry and regulatory perspective. COVID-19 has impacted the industry's ability to conduct trials with broad travel restrictions, concerns about investigative site capacity, and most importantly, patient safety considerations. US and international regulatory bodies have moved quickly to encourage the adoption of remote data capture and telemedicine capabilities with patient and investigator safety as paramount concerns.

[1] Marwood interviewed and surveyed a diverse array of US clinical trial sponsors as well as stakeholders from clinical research organization (CRO) and site management organizations (SMOs) in developing estimates.

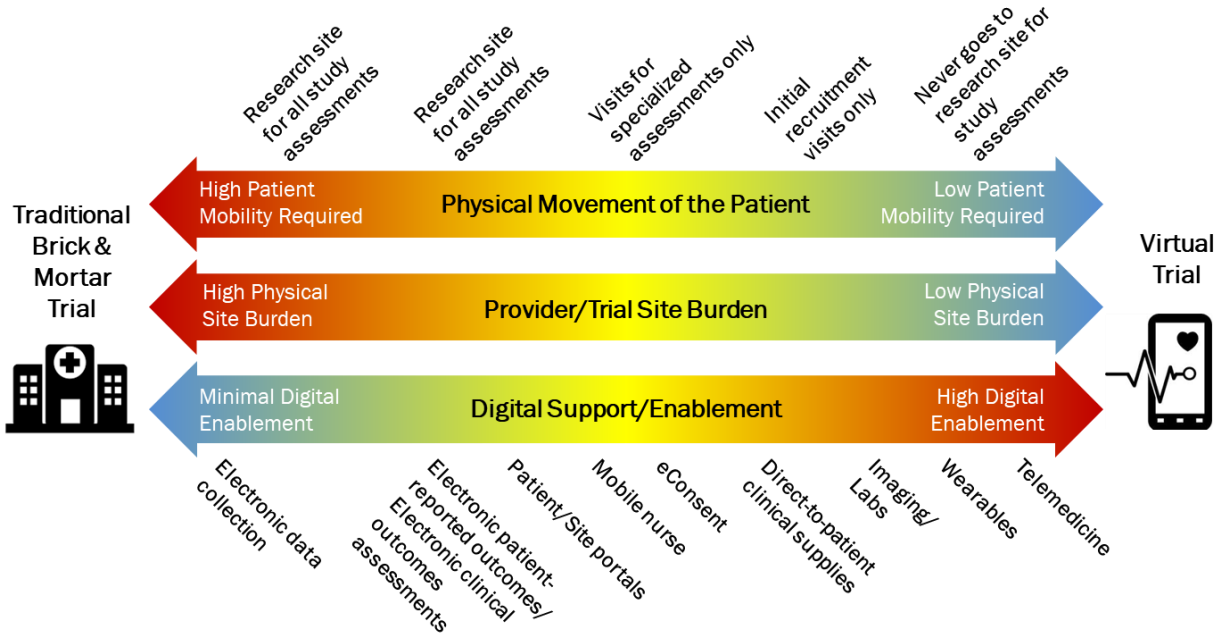

Figure 1: Dimensions to consider when assessing clinical trial virtualization include burden on the patient, provider and digital support/enablement.

II. Advantages of Virtual Clinical Trials

Virtual clinical trials offer an array of advantages that are likely to extend beyond the national health emergency. Intuitively, allowing study participants to visit with clinical staff virtually is safer during the COVID-19 pandemic and also much more convenient and accessible. Going forward, incorporating more virtual components into a trial design could greatly increase not only total recruitment, but access to participants with greater diversity across socioeconomic, ethnic and age demographics willing to participate. By Marwood estimations[1], 30% of patients drop out of conventional clinical trials. Through limiting the extended burden of repeated travel, retention is improved.

Incorporating virtual components into a trial can also help automate manual processes such as site selection and data collection that improve the robustness of clinical results while significantly reducing both the time and cost of a trial. By Marwood estimates[1], 40% of patients do not end up adhering to trial protocols. Simple and intuitive processes, such as smartphone reminders, improve compliance. More advanced technology implementation, such as the array of new sensors and devices available to measure various biological or behavioral events, with minimal effort on the part of the patient, improve the frequency, amount, and accuracy of data collection, providing for more real-world data outside of those snapshots in time when patients are in the clinic.

From a financial perspective, it is about reducing the time, burden and cost of managing patients at the investigator site. By Marwood estimations from KOL discussions[1], patient management is ~80% of trial costs. Adding virtual elements to clinical trials, in effect, allows for expanded trial bandwidth of the traditional brick and mortar facility, assuming efficiencies in electronic data handling. Notably, the element of data handling and security, through automation and reduced human interaction, may by default improve security and regulatory compliance.

III. Areas of Growth

Virtual clinical trials are likely to grow across minimal technical requirement, low risk trials with difficult to recruit populations:

- Dosing that requires minimal support (i.e. oral and to a lesser extent subcutaneous injection, and to a yet lesser extent intravenous administration, where training and support are increasingly required)
- Disease models where adverse events may pose a low risk (i.e. diabetes, NASH)
- Trials requiring a broad and diverse population base including chronic disease models (i.e. diabetes, NASH, pain management, oncology) and post-approval (Phase 4) monitoring
- Mechanism of action similar or identical to existing products (i.e. biosimilars)
- Difficult to recruit patient populations including pediatric, elderly and rare disease, where travel to a brick and mortar site may become an issue
- Non-pharmaceutical trials (i.e. e-cigarette/vaping) where a physician is not mandated to conduct a trial.

IV. Regulatory and Legislative Environment

Marwood believes that the FDA is supportive of virtual clinical trial elements. Recent FDA guidance (March 2020 and updated July 2020) acknowledges that the impact of COVID-19 may require companies conducting clinical trials to consider virtual patient visits or put new processes in place regarding their current protocols. The guidance indicates that whenever possible, for investigators to supplant in-clinic interactions with virtual measures such as phone interviews, self-administration and remote monitoring. Along these lines, the guidance states: "ensuring the safety of trial participants is paramount". However, the guidance leaves the industry wanting, particularly beyond the public health emergency. Gaps include federal regulatory guidelines on compliance expectations and clear guidelines on which types of trials can be virtual.

From an industry perspective, quality management systems (e.g., policies, SOPs and training) and regulatory compliant technologies remain not only to be developed, but a formalized process of qualification provided. Indeed, qualifying of technologies, prior to their use to ensure safety, as well as quality and compliance remain to be standardized; wherein device security is an ongoing concern. Finally, from a state perspective, there remains the issue of telemedicine laws in the context of licensure of physicians, particularly beyond the public health emergency.

Looking forward, it is noteworthy to the virtual clinical trial space that the next round of the Prescription Drug User Fee Act (PDUFA) is currently being negotiated. At the FDA/industry's public meeting held in July 2020, one of the stated stakeholder priorities for the current round of PDUFA, regarding clinical trials, is to get the FDA to agree to build a framework around virtual study sites and remote data collection.

V. Landscape

Broadly, the software-enabled clinical trial space includes not only virtual clinical trial enablement vendors, but players in the broader protocol design, nonprofit & consortia enablement, study start-up, patient recruitment, operations management, drug & supply logistics and patient data management space. Vendor services often extend across categories, further blurring distinctions. Notable virtual clinical trial enablement vendors include familiar clinical research organization (CRO) names such as ICON, IQVIA Virtual Trials, Covance and Parexel. They also include a growing list of players entering directly into the virtual clinical trial space including Curavit Clinical Research, Medidata, Thread Research, Halo Health Systems, Croprime, PRA Health, Science 37, Medable, Lightship, Virtrial, Clinpal, Koneksa and ObvioHealth.

The last year has seen a number of transactions in the space bringing together the biopharma industry and investors. In August of 2020, Science 37, which connects clinical trial participants to researchers via telehealth and a network of home-health nurses, closed a $40M funding round, with investments from Novartis, Amgen and Sanofi Ventures; Lux Capital, Redmile Group and PPD led the round, and LifeSci Ventures and Mubadala Ventures joined in for the first time. In November of 2020, Medable, which provides digital solutions for virtual enablement of clinical trials, raised $91M in funding led by Sapphire Ventures with follow-on investment from existing investors GSR Ventures, PPD and Streamlined Ventures. Evidation, which initially launched as a research app where people can opt into virtual clinical trials, and has since expanded into digital health programs, recently raised $153M in new funding led by Omers Growth Equity and Kaiser Permanente Group Trust.

VI. Conclusions

Marwood routinely considers strategies in the CRO and site management organization (SMO) space as well as the institutional review board (IRB) landscape from the perspective of industry and investigator stakeholders. This is in addition to Marwood's federal analysis of regulatory and legislative actions directly impacting virtual clinical trial enablement as well as indirect impacts from such areas as drug pricing and telehealth. As Marwood explores strategies in the virtual clinical trial space, we continue to follow the impact of the new administration on the sector and associated market dynamics emerging as the pandemic wanes.

About the Author

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