ARTICLE

EDUCATION AND RESEARCH

It's High Time for a Trial Transformation. Are You Ready to Go Virtual?

by Keith Graff, Andrea Wetmore, Ryan Moynihan

ECG MANAGEMENT CONSULTANTS

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The traditional clinical trial model is long overdue for an upgrade.

For years, clinical trials have been burdened by high costs, logistical challenges, limited patient participation, and inadequate panel diversity. As a result, the development of new treatments and therapies has been slow, and patients have been underserved. Fortunately, a new era of clinical research is emerging, where technology is optimized to create a more efficient, accessible, and patient-centric experience.

Virtual clinical trials are at the forefront of this revolution, offering a promising solution to the industry's long-standing challenges. By shifting away from traditional, site-based models, virtual trials can accelerate drug development, expand participant populations, and improve overall trial outcomes. Growth and enhancements in virtual trial capabilities are also contributing to the broader decentralized clinical trials movement, which aims to make clinical research more accessible and efficient for all patients and providers by expanding access beyond traditional sites.

As discussed herein, the benefits of this movement—and virtual trials in particular—are extensive. Health systems should strongly consider incorporating these innovative approaches when establishing or redesigning their research enterprise strategies to improve both patient lives and facility bottom lines.

STRATEGIC RATIONALE FOR DEVELOPING A NONTRADITIONAL RESEARCH INFRASTRUCTURE

The traditional model for conducting clinical trials involves patients visiting a physical site and interacting with study teams for enrollment and study monitoring. While this approach has succeeded in developing treatment protocols for years, it has long been ripe for innovation, considering that from compound discovery through FDA approval, developing a new clinical therapy can take over 10 years and cost between $161 million and $4.5 billion.[1]

This need for change became critical with the onset of COVID-19, which forced the life sciences industry to innovate and adapt to address the new challenges associated with trial management that arose during the pandemic and subsequent recovery era.

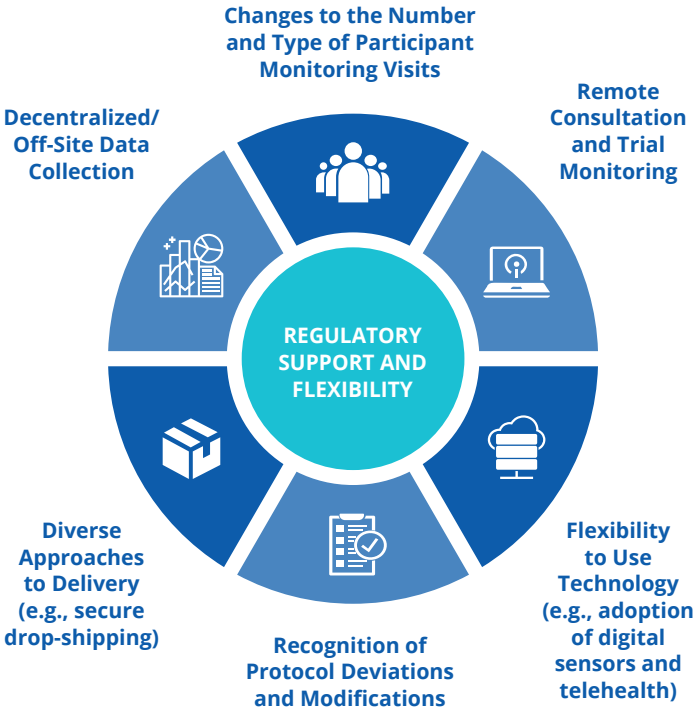
TABLE 1: Clinical Trial Barriers during COVID-19

Workforce	• Workforce reductions due to layoffs and/or employee turnover • Significant increase in remote work • Limited interaction of staff members within and across study teams • Burnout among existing staff due to increased workload • Challenges in conducting sample collection and maintaining data integrity and security in remote settings
Laboratory	• Limited access to facilities and equipment
Supply Chain and Medicinal Adherence	• Home delivery of investigational medicinal product to trial participants (versus historical on-site storage and delivery solutions) • Supply chain disruptions affecting essential reagents and equipment • Challenges in ensuring patient adherence to treatment regimens in a remote setting

The disruptions from COVID-19 highlighted the unsustainability of the site-based model and led to the adoption of new technologies, revised processes, and modified regulatory policies that showed clinical trials could continue virtually while minimizing risks to trial integrity and prioritizing participant safety.

As a result, FDA guidance in 2020 suggested that companies conducting clinical trials should consider transitioning to nontraditional approaches (e.g., decentralized trials; a web-based, site-less research infrastructure) or developing suitable pandemic contingency plans that include virtual patient visits instead of in-person ones. ▶

FIGURE 1: Regulatory Agency Support for Clinical Trial Flexibility



WHAT IS A VIRTUAL CLINICAL TRIAL?

The primary difference between virtual clinical trials and traditional clinical trials is where and how data is collected. Whereas traditional clinical trials require patients to visit a clinic and researchers to rely on an intermediary to collect the study data at a physical location, a virtual clinical trial relies on digital health technologies (i.e., mobile devices, apps, remote monitoring devices, and online engagement platforms) to collect information at each stage of the trial.

The use of these technologies improves recruitment and retention of trial participants and enables online-based, informed consent; measurement of real-time clinical endpoints; and continuous tracking of adverse events. As such, virtual clinical trials are more coordinated and offer a better overall experience for participants.

BENEFITS OF VIRTUAL CLINICAL TRIALS

Virtual visits are unlocking the potential for research to be conducted at unprecedented scale, and the associated convenience and enhanced accessibility are likely to lead to increased participant retention and better data collection.

- **Faster Recruitment and Enrollment:** Globally, over 80% of clinical trials fail to meet enrollment targets on time and 55% of terminated trials are due to low accrual rates.[5] The virtual clinical trial model can provide efficiencies and cost-effectiveness in recruiting and screening patients, which allows organizations to meet their enrollment numbers faster. For example, the traditional trial model makes finding individuals with specific genetic mutations nearly impossible. And even if they are identified, these individuals often live geographically distant from study centers. However, AI-enabled technologies can identify a patient population with specific criteria for clinical trials within minutes, accelerating what has historically been a months-long process.
- **Increased Patient Reach and Participant Diversity:** The traditional clinical trial model involves selecting a physical trial site and then trying to recruit enough patients to travel to that site. On average, US participants travel more than 50 miles for their trial site visits.[2] The extensive travel required is a primary contributor to both low participation rates and the

FIGURE 2: Clinical Trial Continuum

TRADITIONAL TRIALS

- Conduct trial visits primarily on site with principal investigators (PIs) and study coordinators (SCs).
- Enhance traditional study designs with patient insights to remain patient focused and ease the study burden.
- Use standard patient recruitment and retention tools and services.

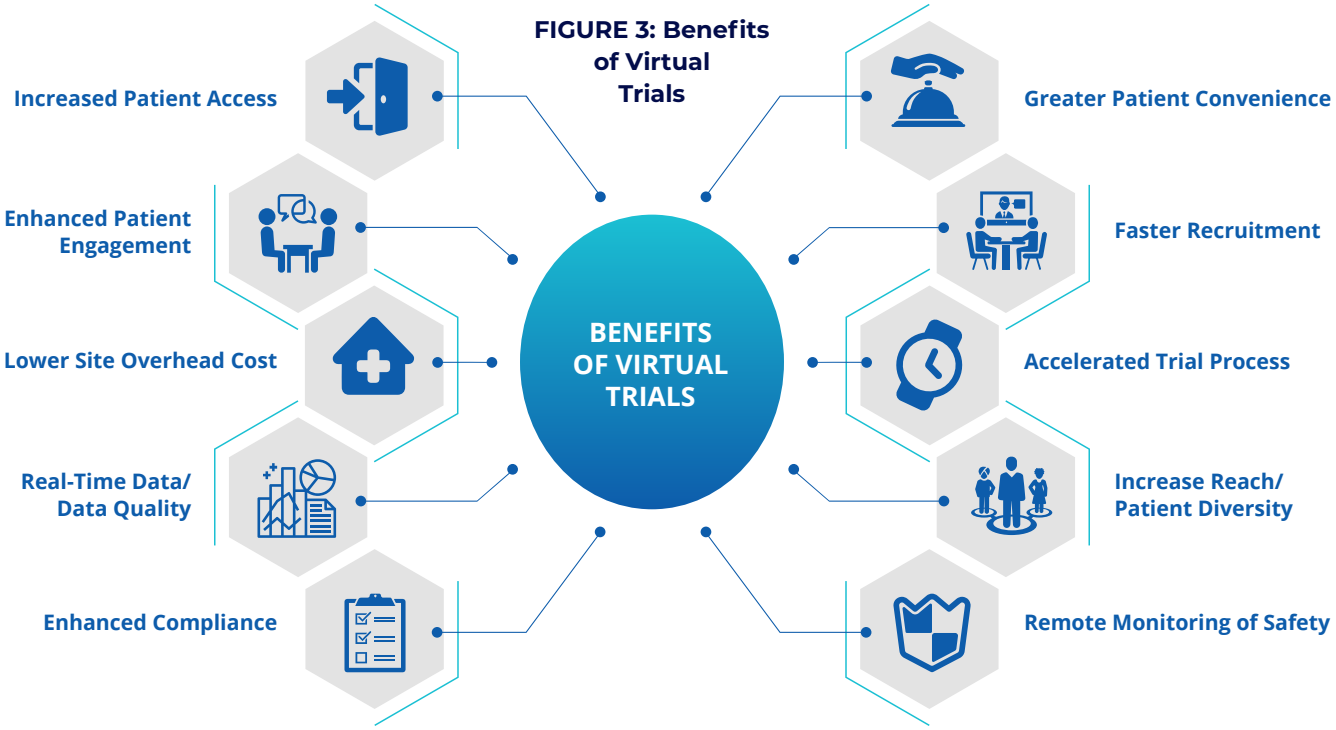
HYBRID VIRTUAL TRIALS

- Deploy relevant virtual clinical trial elements to offset site visits for participants and meet end points.
- Limit the number of and/or reduce the length of site visits.
- Use digital patient and caregiver engagement tools for study conduct and standard patient recruitment and retention tools and services.

FULLY VIRTUAL TRIALS

- Conduct entire trial from the participant's home, eliminating site visits.
- Utilize remote PIs/SCs.
- Deploy digital patient and caregiver engagement tools.

FIGURE 3: Benefits of Virtual Trials



limited diversity of trial participants. As such, improving these factors can help trial administrators meet their enrollment goals.

- **Greater Patient Convenience:** Virtual trials allow researchers to take the trial to the participant, enhancing comfort, convenience, and confidentiality. Under the virtual trial model, patients can connect with PIs or study team members from their home or office through technology, similar to telehealth services. If a data sample is required—for example, a blood draw—a home health nurse can travel to the patient and collect the sample.[3]
- **Lower Site Overhead Costs:** A virtual clinical trials network can significantly reduce overhead costs for health systems by eliminating the need for dedicated space, equipment, and utilities. Additionally, fewer on-site staff are required for patient management and data collection, leading to lower personnel costs. These savings can be used to invest in other critical areas, such as patient care, research, or infrastructure improvements.
- **Increased Patient Access:** Virtual trials enable participation primarily from home, are better able accommodate individual schedules, and significantly ease travel burdens, collectively reducing the geographic barriers associated with traditional site-based trials. This enhanced patient experience activates greater involvement from historically hesitant groups[4] and can diversify participant pools, enabling recruitment from both rural and urban underrepresented populations often residing in remote or socioeconomically disadvantaged areas.
- **Accelerated Trial Process and Enhanced Patient Engagement and Retention:** Prospective patients can complete a profile through digital mechanisms, such as a smartphone app designed for the study; virtually provide consent; and complete initial screenings through online surveys, phone calls, or telehealth visits initiated by trial team members. Furthermore, the accessibility and convenience of virtual trials can increase patient enrollment, compliance, and retention, allowing for a more streamlined trial process. ▶

User-friendly clinical trial apps further improve the ability to rapidly enroll large patient populations. For example, Stanford's MyHeart Counts Cardiovascular Health Study, an Apple ResearchKit app study, obtained consent from 48,968 participants in just six months.[6]

- **Real-Time Data Collection and Improved Data Quality:** Beyond patient enrollment, virtual trials help address challenges with patient evaluation. In a virtual trial, mobile technologies and sensors provide new and improved ways to collect data, providing a more comprehensive picture of the participant's condition. Sensors within portables, wearables, and implantable devices can continuously track specific symptoms to make data collection more objective and frequent. Additionally, sensors and app-based algorithms can detect responses to medications and give researchers better insight into drug effectiveness and dosage impact. In virtual trials, data collection isn't limited to the sporadic and manual entries taken in an office setting—data can be gathered continuously and automatically throughout the day.
- **Enhanced Compliance and Remote Monitoring of Patient Safety:** Finally, virtual clinical trials further promote patient adherence and compliance with study protocols. Both the validity of the trial and patient safety are at risk when participants fail to comply with protocols. Telehealth access lets PIs have short, frequent interactions with participants to ensure early and continued compliance by answering questions, issuing reminders, and addressing root causes of noncompliance. For example, by visually examining the medication bottle via a live video, a PI can assess how many doses have been taken to gauge administration compliance.

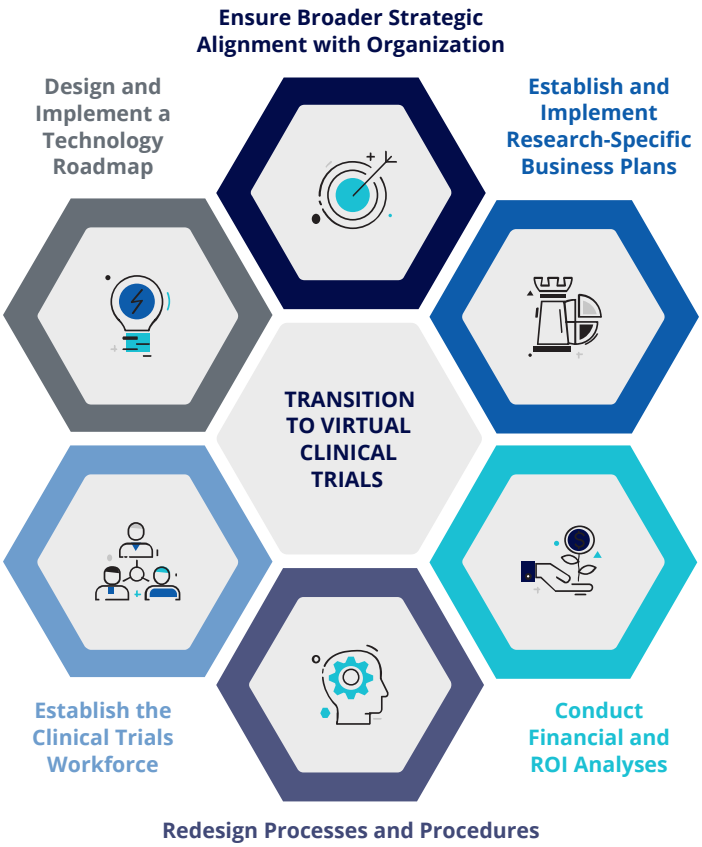
RECOMMENDATIONS FOR DEVELOPING A VIRTUAL VISIT INFRASTRUCTURE

Although virtual studies and research technologies have advanced rapidly, they are not without their own set of risks. Key concerns include sharing of sensitive health information over the internet (patient privacy, HIPAA con-cerns, and cybersecurity concerns); navigating technical barriers (such as adopting and learning how to use new digital health technology user interfaces); and managing the necessary cultural changes associated with these new technologies.

Organizations should incorporate the six recommendations below to support a smooth technical and cultural transition for researchers and their patients when implementing virtual clinical trials.

- **Recommendation One:** Ensure that the rationale for adopting a virtual trial aligns with your organization's strategic, clinical, and academic vision.
- **Recommendation Two:** Develop and implement strategic research business plans that integrate virtual research components into routine clinical practice (e.g., scheduling virtual trial follow-up assessments and virtual medical visits).
- **Recommendation Three:** Conduct an ROI analysis to understand what operational efficiencies can be achieved, as well as the associated cost savings. For example, fewer physical trial sites means lower start-up and maintenance costs, less personnel expense, and reduced travel costs.
- **Recommendation Four:** Revise existing policies and standard operating procedures to support the coordination of virtual processes.
- **Recommendation Five:** Develop and equip a robust, centralized clinical trials workforce with the appropriate resources, training, and incentives. Since decentralized trial models promote the use of a single "virtual" PI and a large geographic footprint for trial participants (i.e., nationwide), modified requirements and tactics may be needed when developing participant and PI recruitment plans.
- **Recommendation Six:** Design a technology roadmap to determine the tools, products, and interfaces required to administer trials virtually. Comprehensive

FIGURE 4: Elements of a Smooth Transition to Virtual Clinical Trials



digital platforms and technology partners that aid with virtual data collection; patient selection, monitoring, and analysis; and clinical trial management will need to be evaluated prior to selection.

THE PATH FORWARD

As a result of post-pandemic recovery challenges and other industry pressures, provider resources continue to be stretched and patients' demand for convenient care is increasing. Organizations conducting clinical research should continue to assess financial and regulatory considerations and invest in technologies that will accelerate the decentralization of clinical trials and increase the resilience of their research programs.

The development of a virtual research infrastructure provides an opportunity for organizations to ensure patient safety, realize efficiencies, and overcome the obstacles presented by maintaining a traditional clinical trial model in the modern healthcare environment. ■

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AUTHORS

KEITH GRAFF
Principal
kagraff@ecgmc.com

ANDREA WETMORE
Associate Principal
abwetmore@ecgmc.com

RYAN MOYNIHAN
Manager
rtmoynihan@ecgmc.com