

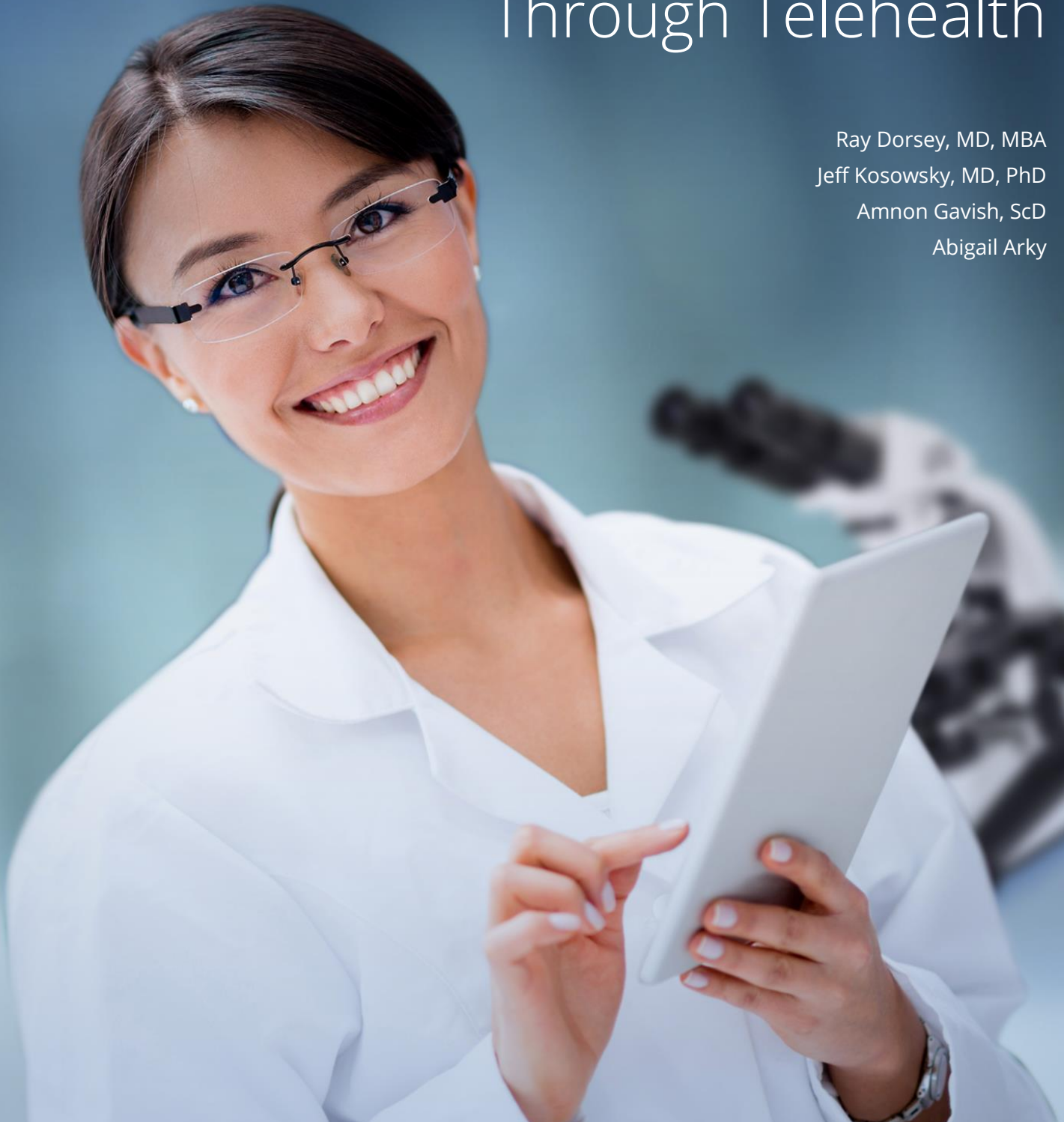
Transforming Clinical Trials Through Telehealth

Ray Dorsey, MD, MBA

Jeff Kosowsky, MD, PhD

Amnon Gavish, ScD

Abigail Arky





Introduction

Telehealth has expanded access to healthcare, delivered high quality, effective outcomes for patients, and allowed clinicians to connect more easily with patients and manage their treatments. Initially used to connect remote patients to clinicians for emergencies (e.g., stroke), telehealth has extended to include urgent care, chronic care, post-surgical follow-up appointments, remote patient monitoring, behavioral health and more.

As telehealth has expanded and become more ubiquitous in delivering healthcare, the same technology can be applied to improve clinical trials. High-quality, real-time video visits have the potential to transform the outcomes and success for clinical trials, just as they have done for traditional care. The opportunity size is large – both from the standpoint of enhancing the efficiency of an individual trial and for transforming the trial industry. Organizations from pharmaceutical companies to contract research organizations to large health systems are harnessing the power of telehealth to support clinical trials at all stages.

Key steps to setting up a successful telehealth program for a clinical trial include access to the necessary technology and services, establishing a core team, and defining use cases. The right technical infrastructure will provide both patients and researchers with the tools they need to conduct an informed virtual encounter. Most often, this requires a strategic partnership with a third-party telehealth vendor. And while technology partnerships are a critical starting point, it's just as important to designate a telehealth leader and committee within the research organization. Once established, this team should work to identify the right trial stages to implement telehealth, such as recruitment or enrollment. It is best to start small and simple, track progress and adjust workflows as needed, all while continuing to educate and connect stakeholders so the telehealth solution improves the accessibility, design and outcomes of the clinical trial.

Telehealth Addresses Healthcare Challenges

Enhancing access to care

Telehealth removes geographic barriers to care providers, particularly with specialists. Specialists are unevenly distributed throughout the country, with the majority located in major cities. This presents a problem for the 25 percent of the U.S. population that lives in rural areas.¹ Limited access to providers results in lengthy delays between the identification of a need for specialist care and a scheduled appointment. Telehealth eliminates access challenges as patients can receive high quality specialist care from their homes through live video visits, whether scheduled or on-demand. For example, a stroke patient is no longer required to travel to a clinic for follow-up care.

Addressing long wait times

Current medical care is inconvenient.² A recent study found that patients spend 121 minutes traveling and waiting to see a provider, while the average physician encounter lasts just 15 minutes.^{3,4} Telehealth streamlines the delivery of care for patients and clinicians. The average wait time to see a provider is less than five minutes on Amwell, and the average visit length is fifteen minutes, including provider wrap-up.⁵

Reducing high costs associated with healthcare

The current healthcare system is plagued by high costs for both patients and health systems. Hospital readmissions are a primary cost driver. Medicare spends \$27 billion each year on hospital readmissions, and \$17 billion is spent on readmissions that are potentially preventable.⁶ Telehealth helps hospitals reduce readmission rates and the costs associated with them by improving follow-up care.⁷ Telehealth makes it easier to regularly monitor high-risk patient populations, such as chronic care patients and those with diabetes through short, live interactions.

A healthcare study sponsored by Anthem found that Anthem's LiveHealth Online virtual video visits are a low-cost alternative to traditional urgent care. Patients had fewer hospitalizations and visits to the ER within a three-week period after the visit than individuals who received care from a clinician in person. Urgent care centers, primary care providers, and emergency departments were estimated to be \$153, \$162, and \$1735 more expensive than LiveHealth Online virtual visit episodes, respectively, including medical and pharmacy costs.⁸ Telehealth enables these savings by eliminating travel, reducing overhead, and allowing for frequent interactions between patients and clinicians.

A study by Southwest Medical, part of OptumCare in Nevada, found that for virtual visits for upper respiratory infections, only 4 percent of patients had to return for a follow-up visit. In the case of in-office visits, 26 percent returned for a follow-up visit.⁹ By reducing the cost of initial visits and the need for follow-up visits, telehealth is already delivering a twofold savings.

AVERAGE
PATIENT SPENDS
121
MINUTES
TRAVELING & WAITING
TO SEE A DOCTOR

AVERAGE IN-PERSON
VISIT TAKES
15
MINUTES

AVERAGE TELEHEALTH
WAIT TIME IS
5
MINUTES

¹ UnitedHealthcare, UnitedHealthCare Consumer Sentiment Survey: 2017 Executive Summary, 2017.

² Mehrotra A. The Convenience Revolution for Treatment of Low-Acuity Conditions. *JAMA: the journal of the American Medical Association*. 2013;310(1):35-36.

³ Ray KN, Chari AV, Engberg J, Bertolet M, Mehrotra A. Disparities in Time Spent Seeking Medical Care in the United States. *JAMA internal medicine*. 2015;175(12):1983-1986.

⁴ Ray KN, Chari AV, Engberg J, Bertolet M, Mehrotra A. Opportunity Costs of Ambulatory Medical Care in the United States. *Am J Manag Care*. 2015;21(8):567-574.

⁵ American Well, 2015.

⁶ National Investment Center, Readmissions & Medicare: What's the Cost?, 23 March 2016.

⁷ O'Connor M, Asdornwised U, Dempsey ML, Huffenberger A, et al. Using Telehealth to Reduce All-Cause 30-Day Hospital Readmissions among Heart Failure Patients Receiving Skilled Home Health Services. *Appl Clin Inform*. 2016;7(2):238-47.

⁸ Gordon AS, Adamson WC, DeVries AR. Virtual Visits for Acute, Nonurgent Care: A Claims Analysis of Episode-Level Utilization. *J Med Internet Res*. 2017;19(2):35.

⁹ Tan LF, Mason N, Gonzaga WJ. Virtual Visits for Upper Respiratory Tract Infections in Adults Associated with Positive Outcome in a Cox Model. *Telemed J E Health*. 2017;23(3):200-204.

The Rationale for Telehealth in Clinical Trials

Clinical trials and pharmaceutical research face many of the same time and resource consuming challenges that plague healthcare. Additionally, the productivity of drug development has been declining for 50 years so novel methods to lower costs and improve efficiency in trials are needed.

Address difficulties recruiting, screening and enrolling patients

Current clinical trials are inaccessible to many patients. In a survey conducted by Memorial Sloan Kettering Cancer Center involving more than 1,500 participants, only 35 percent were “likely” to enroll in a clinical trial. Almost half indicated that the location of the trial sites were inconvenient and made them unlikely to participate.¹⁰ The results are long recruitment times and difficulties accessing key sub-populations of patients.

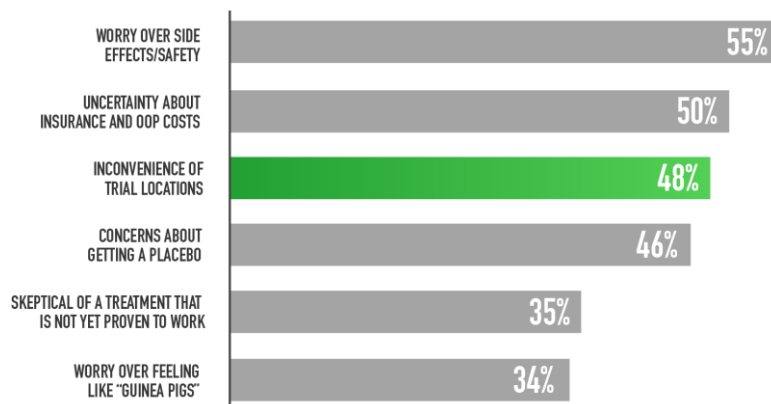


Figure 1. Most frequently cited barriers to clinical trial participation among Americans.¹¹

Common barriers to recruitment include the patient’s severity of disease, age, social circumstances, location and language. The current trial model makes finding individuals with specific genetic mutations nearly impossible, and even if they are identified, these individuals are often far from study centers. Researchers want to use telehealth to reach these populations and improve the speed of recruitment and enrollment. 23andMe and the Michael J. Fox Foundation for Parkinson’s Research conducted a proof of concept study which showed that geographically distant populations with the same genetic disorder and underlying genotype can be identified, monitored, and engaged through remote assessment.¹² This study opens the door to larger scale studies involving genetic sub-populations using virtual trials to enroll geographically dispersed populations.

Telehealth streamlines the screening process. Traditionally, potential participants must travel to a research site for an in-person screening visit. With telehealth, screening is more efficient and cost effective. Prospective patients can complete a profile on the study app and virtually provide consent. Initial screening is completed through online surveys and voice calls to collect contact and health information. Trial team members can initiate a telehealth visit to evaluate the participant’s clinical health.

Virtual trials have already given researchers access to large and diverse patient populations to increase the efficiency of recruitment, screening, and enrollment. A study with Fox Trial Finder, an online registry created by the Michael J. Fox Foundation for individuals with Parkinson’s disease, performed consenting via phone calls and used video conferencing software to conduct remote assessments of 166 Parkinson’s patients in

¹⁰ Advisory Board, Why don’t patients enroll in clinical trials?, 17 October 2016.

¹¹ Advisory Board, Why don’t patients enroll in clinical trials?, 17 October 2016.

¹² Dorsey ER, Darwin KC, Mohammed S, Donohue S, et al. Virtual research visits and direct-to-consumer genetic testing in Parkinson’s disease. *Digital Health*. 2015;1:1-18.

39 states. Over 80 percent of participants said they would be more willing and able to participate in future research studies if they could do so remotely.¹³

Creating easy to download clinical trials apps further improves the ability to rapidly enroll large patient populations. For example, Stanford's MyHeart Counts, an Apple ResearchKit app study, consented 48,968 participants in just six months.¹⁴ Virtual visits are already enabling remote participation in trials, unlocking the potential for research to be conducted at unprecedented scale and scope.

Address challenges with patient evaluation

While large patient populations are often desired, the periodic collection and entry of data can overload trial investigators. Typically, researchers might collect data from a patient once or twice a month, providing a snapshot of the patient's condition at the time of the appointment, not an understanding of their overall health. As a result, endpoints are often subjective, episodic, and insensitive.

Mobile technologies and sensors provide new and improved ways to collect data and measure endpoints, providing a more complete and comprehensive picture of the participant's condition. These technologies also enable novel endpoints that previous data collection methods were not able to assess. Sensors such as portables, wearables, and implantable devices can continuously track specific symptoms to make data more objective, sensitive, and frequent. Sensors and app-based algorithms can detect responses to medications and give researchers better insight into drug effectiveness and dosage.



Remote monitoring devices improve data collection and evaluation

Enhance centralized evaluation

Current clinical trials often involve multiple sites with many investigators, leading to increased assessment variability. This potential for variability increases the number of patients needed to yield statistically accurate results, along with the expense and failure rate of such trials.

The workflow of virtual clinical trials allows for consistent, rating and assessment by a small, centralized group of expert raters, reducing the potential for bias and variance. Trials can thus be conducted with smaller samples, lower costs, less variability, and greater likelihood of success. A recent trial used remote video assessments by centralized raters and led to the approval of a new anti-psychotic medication.¹⁵



Virtual trials enable centralized evaluation and ratings

Increase retention of participants

Retention is a key barrier to clinical trial success. According to CenterWatch report, drop-out rates can range from 15 to 40 percent.¹⁶ For example, elderly or physically disabled individuals may cease participation if

¹³ Dorsey ER, Wagner JD, Bull MT, Rizzieri A, et al. Feasibility of Virtual Research Visits in Fox Trial Finder. *J Parkinsons Dis.* 2015;5(3):505-515.

¹⁴ iMedical Apps, MyHeart Counts, ResearchKit app study, releases initial results, 16 December 2016.

¹⁵ Cummings J, Isaacson S, Mills R, Williams H, et al. Pimavanserin for patients with Parkinson's disease psychosis: a randomized, placebo-controlled phase 3 trial. *The Lancet.* 2014;383(9916):533-540.

¹⁶ Applied Clinical Trials, Subject Recruitment and Retention: Barriers to Success, 1 April 2004.

frequent in-person visits and assessments are required. In long trials, participants and investigators may relocate or become harder to reach. Low retention rates contribute to longer and larger trials, lower staff and participation satisfaction, less statistical power, and higher costs. In some cases, low patient recruitment and retention can lead to a failed clinical trial.

With telehealth, enrolling in a trial no longer means periodic visits to the study site. In a pilot study on virtual visits involving participants with Huntington's disease, 82 percent of individuals from 10 states completed the virtual visits with an overall satisfaction of 93 percent.¹⁷

Ensure compliance

The validity of a trial and patient safety are at risk when participants fail to comply to protocol. Telehealth access lets investigators have short, frequent interactions with participants to ensure early and continued compliance by addressing questions, issuing reminders, and addressing root causes of non-compliance. For example, by visually examining the medication bottle via live video, an investigator can assess how many doses have been taken to gauge administration compliance.

Address deficiencies in coordinated care with licensed clinicians

Good clinical practice in research does not guarantee good clinical care. The trial investigators must protect the rights, safety, and welfare of participants, but they are not mandated to give them medical care. For this reason, it is paramount to provide participants with coordinated medical support throughout a clinical trial.



Provide coordinated care through a telehealth platform

Telehealth makes it easy to coordinate research with clinical care by overlaying virtual clinical visits under the direction of licensed primary care and specialist physicians. Patients, clinicians, and researchers can communicate about the interacting clinical and research aspects of their care, such as potential side effects of a study drug or other medical issues. If necessary, a virtual clinician, who is aware of the study protocol, can intervene to provide immediate care and communicate any changes in status or treatment to the study investigators. The trial team can then determine if these changes impact eligibility and outcome measures.

Enhance post-trial longitudinal follow-up

The need for long-term follow-up in clinical trials is increasing and in certain cases, is mandated.¹⁸ Some investigational biological therapies may require safety assessments for up to a decade. However, few clinical trials have long-term follow-up data and such follow-up is burdensome for participants and expensive for sponsors, especially as populations move and disease burden increases

Virtual clinical trials facilitate long term longitudinal patient follow-up for phase IV and post-approval safety data by increasing the ease of follow-up. Apps on smartphones can continue to monitor patient symptoms after the primary endpoint of the trial, and researchers can automatically program follow-up surveys for months to years in the future. In addition, virtual research visits can connect to participants wherever they are located, even as their disease burden increases making in-person follow-up more difficult.

Improve economics associated with physical trial sites

Clinical trials are expensive and direct financial costs are enormous. A phase three trial can cost \$50 million with larger ones running into hundreds of millions of dollars.¹⁹ The time costs are even larger.²⁰ Each day of

¹⁷ Bull MT, Darwin K, Venkataraman V, Wagner J, Beck CA, et al. A pilot study of virtual visits in Huntington disease. *J Huntingtons Dis.* 2014;3(2):189-195.

¹⁸ U.S. Food and Drug Administration, Guidance for Industry: Gene Therapy Clinical Trials – Observing Subjects for Delayed Adverse Events, 2006.

¹⁹ Sertkaya A, Wong HH, Jessup A, Beleche T. Key cost drivers of pharmaceutical clinical trials in the United States. *Clin Trials.* 2016;13(2):117-26.

²⁰ DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ.* 2016;47:20-33.

delay can cost a sponsor up to \$8 million²¹ while a failed clinical trial can cost companies \$800 million to \$1.4 billion.²²

Virtual clinical trials reduce the number of trial sites needed and the associated costs required for start-up and maintenance. Fewer personnel are needed to run a centralized virtual trial, further driving down costs. Participants and members of the research team can access the trial from a mobile device or the web, reducing costs for travel. Reduced dropout and improved compliance allow for smaller trial size. Virtual follow-up visits reduce wait times and provide the trial team with up-to-date information before the visit so time is better utilized. Telehealth clinical trials have the potential to integrate with wearable sensors to perform real-time monitoring, providing high frequency objective data that is less likely to cause false signals and may enable quicker assessments of efficacy.²³

Current Uses of Telehealth for Clinical Trials

Initial clinical trials that use telehealth show promise and early indications suggest that telehealth will be a game changer in terms of the quality of results and cost savings.

Pfizer conducted one of the first entirely remote clinical trials.²⁴ With no in-person visits, only one research site, and assessments all conducted remotely, Pfizer demonstrated the feasibility of such an approach.

Nemours Children's Health System, based in Jacksonville, Florida, but with a global reach, leverages its American Well telehealth platform to offer video visits for spinal muscular atrophy clinical trials. Neurologist Dr. Richard Finkel uses video visits to work with a physical therapist to judge whether an infant patient would be the ideal candidate for upcoming drug studies. Telehealth removes the barriers of physical location allowing parents all over the world to enroll their children in valuable and potentially life-saving studies.

Researchers at the University of Rochester are using mPower, a mobile app developed with Sage Bionetworks, to collect real-time data from Parkinson's patients, including a phase 3 clinical trial. Voice, posture, gait, and memory tests accessed through the app can distinguish those with Parkinson's from those without the disease and have enough sensitivity to detect responses from medications.²⁵

Researchers have partnered with innovative companies to improve recruitment for trials. Biogen Idec partnered with 23andMe to assess the phenotype of 50 individuals in 23 states in a virtual research study.²⁶ The speed and accuracy in which they were able to assess these patients is critical for future studies.

²¹ eMedonline, Pharmaceuticals, 2012.

²² Clinical Leader, The High Price Of Failed Clinical Trials: Time To Rethink The Model, 3 October 2016.

²³ Dorsey ER, Papapetropoulos S, Xiong M, Kieburtz K, The First Frontier: Digital Biomarkers for Neurodegenerative Disorders. *Digit Biomark* 2017;1:6-13.

²⁴ Orri M, Lipset CH, Jacobs BP, Costello AJ, Cummings SR. Web-based trial to evaluate the efficacy and safety of tolterodine ER 4 mg in participants with overactive bladder: REMOTE trial. *Contemporary Clinical Trials*. 2014;38(2):190-197.

²⁵ Bot BM, Suver C, Neto EC, Kellen M, et al. The mPower study, Parkinson disease mobile data collected using ResearchKit. *Sci Data*. 2016;3:160011.

²⁶ Dorsey ER, Darwin KC, Mohammed S. Virtual research visits and direct-to-consumer genetic testing in Parkinson's disease. *Digital Health*. 2015;1:1-18.

The Size of the Opportunity

The full scope and scale of how virtual clinical trials will affect the research industry are yet to be seen, as is the return on investment of telehealth in the trial setting. The average cost to develop a drug, including the cost of failures was \$179 million in the 1970s. Today the cost is \$2.6 billion.²⁷ Monitoring makes up 25 to 30 percent of the overall cost of clinical trials. It is projected that risk-based monitoring, an approach made easier with telehealth, will return a reduction in monitoring expenses by 15 to 20 percent.²⁸ Certain trial types are more suitable for a virtual setting. Studies involving genetic subpopulations and large, nationwide populations are made possible through remote trials. Observational studies, late-phase trials, and real-world evidence studies are also well suited as they are often lower risk. We can only begin to estimate the extent to which integrating telehealth across multiple trial stages will drive down costs, but the potential impact is large.

Building the capability to conduct virtual trials requires some initial investment, however, the eventual efficiencies will easily outweigh the startup costs. Sponsors will have to acquire and implement the necessary telehealth platforms to support virtual visits. While both providers and participants can access visits with standard PCs and mobile devices, there may be a need to outfit participants with monitoring peripherals. Training and organizational support for study sites and providers will also be required. In addition, “siteless” studies may have other costs (e.g., visiting nurses) that are not present in clinical trials. These costs are minimal compared to the potential savings in time and money.



PATIENT CENTRIC CARE



INCREASED TIME SAVINGS



INCREASED COST SAVINGS



INCREASED EFFICIENCIES

²⁷ DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ.* 2016;47:20-33.

²⁸ Ray S, Clinical Teams Should Re-Think Risk-Based Monitoring Costs to Improve Their Bottom Line, *Cutting Edge Information*, 2013.

Developing and Implementing Telehealth Trials

The technologies required for a virtual clinical trial are now widely available. Start small and simple – organizations do not have to launch with an end-to-end solution but can integrate the technology into specific stages, starting with enrollment or data collection. The following roadmap can kickstart a virtual clinical trial.

1. Select a telehealth technology partner to implement the platform and power a virtual clinical trial, a project investigator and team of researchers, and a central location to manage regulatory materials.
2. Establish a dedicated telehealth leader and committee. Identify key stakeholders in all departments, including patients, caregivers, physicians, researchers, foundations, and representatives of pharmaceutical companies. Encouraging key stakeholders to actively participate in the design and execution of virtual trial technologies from day one dramatically improves the overall likelihood of success.
3. Define goals before adding telehealth into clinical trial design. What will telehealth help you achieve? What efficiencies and improvements will it add? Include telehealth workflows in a clinical trial design and show how they can achieve and improve primary and secondary outcomes.
4. Identify and target uses for telehealth technologies in the context of a trial protocol. Highlight a few stages that can be launched quickly, such as patient recruitment and enrollment. Be realistic about what can initially be accomplished and use the first phase to test and learn.
5. Meet with the technology partner's engineering team to make a plan around integrated solutions. Consider EHR and data record integration options. Map out workflows, staffing and scheduling capabilities.
6. Educate and continually engage with the investigative team and physicians. Identify clinical champions as they will help clinician buy-in. Set up discussions among clinicians and the clinical trial team to gauge their interest and determine barriers. Establish best practices and engagement programs to maintain high quality outcomes with telehealth technologies.
7. Use reporting tools to track all aspects of the virtual clinical trial. Measure progress and outcomes through methods like participant satisfaction and the reliability, validity, and sensitivity of virtual processes.
8. Plan how to further implement telehealth into the clinical trial. Learn from results to adapt and broaden current programs by adding technologies into relevant trial stages.

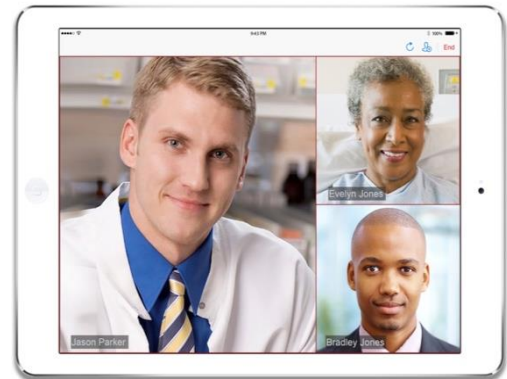


What to look for in a Technology Partner

Given the rigors of clinical trials, a pharmaceutical company or clinical research organization needs a telehealth offering that is more than a teleconferencing service alone or a partnership with a company focused on “site-less” clinical trials. Identify a vendor who is experienced in technology and clinical services, and who will act as a deployment and implementation partner.

Patient experience

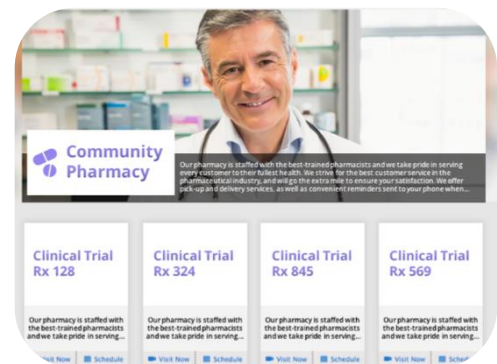
The prevalence of virtual clinical trials is increasing, but the patient experience must be consumer friendly and engaging in order to succeed. The technology must be intuitive and simple for patients to use, without requiring specific training or instruction manuals. The patient flow needs to be highly intuitive and walk the patient naturally through the information they need to provide. If multiple investigators are involved, the platform should allow the participant to choose which one they want to see, and to see the same investigator for follow-up appointments. Multiway video lets participants virtually include remote caretakers to the appointment to ensure they are following the treatment regimen.



Multiway video

Enterprise platform

Enterprise-level functionality allows you to use a single, integrated platform to host multiple, independent trials of unlimited size and scope. Such functionality is also capable of supporting a broad range of clinical and research workflows across disease states and study designs. A white-labelled telehealth solution allows an organization to configure multiple trials on one platform and create a service key that makes the trial accessible only to the eligible patient population. To create a coordinated care network within a trial, the vendor should provide access to a team and operations center that has experience developing a telehealth network, expertise in physician training and clinical protocols, and supports quality assurance, credentialing, and scheduling.



A branded telehealth platform can host multiple clinical trials

Clinical experience

In addition to delivering an Enterprise-level platform, it is equally important that a technology partner bring broad and detailed clinical telehealth experience across multiple use cases and disease states. A partner should have access to a national, 24/7/365 physician network that is board-certified, multi-state licensed and credentialed to NCQA/URAC standards. A multi-disciplinary network that includes nutritionists and behavioral therapists as well as other specialists, such as dermatologists, cardiologists, and neurologists, will ensure that a range of clinical trial types and associated clinical needs are supported. Patient-centered care is a primary driver for the adoption of telehealth in clinical trials, so this physician group should be uniquely trained and experienced in telehealth. Patients are accustomed to interacting with physicians during medical appointments and expect the nature and quality of their interactions with trial investigators to be similar, so partnering with a vendor who is experienced in clinical practice and workflows will keep patient experience at the forefront.

Integrations and software development kits

Integrations and a mobile software development kit (SDK) allows organizations to seamlessly embed telehealth visits into existing trial websites and mobile apps without disrupting the patient experience. Patients only need to log in once to access the clinical trial platform. Look for a platform that integrates with your scheduling system and EHR. Administrative staff can configure multiple visit lengths within the system so the research team can choose an appropriate visit length for each stage of the clinical trial. Study investigators can set recurring appointments to make follow-up visits simple to schedule. Notifications can be sent to remind participants of an upcoming visit to help prevent no shows. A telehealth platform that integrates with multiple EHRs and remote devices improves both the patient and investigator experience by reducing the amount of paperwork and questionnaires and safely sharing data among the clinical trial team, care providers, and patients.

Workflow that can be tailored for clinical research

A telehealth platform should mimic and simplify project investigator workflows. Before a visit, the investigator can review the participant's record, past visit history, and any relevant vitals shared. After the visit, the investigator fills out a visit summary, using a range of definable templates. These fields are configurable based on the data necessary for the study. Files, labs, and images can all be linked to the participant's record. Multiway video allows a researcher to bring in other members of the research or care team as appropriate. A study investigator can virtually "warm" transfer the participant to a clinician if additional clinical care is needed.



A single platform streamlines investigator workflows

Breadth and depth of partnerships

Select a vendor who actively partners with key players in the pharmaceutical, technology, and healthcare industries. A vendor who brings relationships with leading mobile and internet companies has the potential to attract many trial participants from their existing base of hundreds of millions of daily users. Similar advantages apply to relationships with health plans and health systems providing access to broad swaths of the domestic population. Partnerships with device and monitoring companies allow for the integration of advanced sensors and monitoring programs to enhance the volume, accuracy, and relevance of data collected. When a technology partner has an ecosystem of partners that span from consumer destination sites to health plans and health systems to remote patient monitoring and device manufacturers, trial success can be further enhanced from initial recruitment through data monitoring to follow-up.

Conclusion

Just as telehealth has transformed clinical care by increasing access, reducing burden, and lowering costs, telehealth is poised to do the same for clinical trials. The result will be faster, less burdensome, less costly and more powerful trials that accelerate therapeutic development.

Powerful examples already exist of how hospitals and care delivery networks have realized success with telehealth to drive enrollments, improve patient and provider satisfaction, and lower costs. Patients have not only welcomed seeing a doctor via video visit, but an estimated 50 million Americans would switch primary care providers in return for access to video visits.²⁹ Similar trends are developing for remote clinical trials. One study found that 69 percent of participants would prefer to take part in virtual trial again rather than participate in a study that used other methods of data collection.³⁰ Trial participants have the opportunity to benefit from the flexibility and convenience of telehealth while also feeling supported and informed through high-quality, real-time video visits.

Follow the keys to success to set up a telehealth program. Consideration of a telehealth partner is key, and selecting a vendor comes down to four key factors: a successful telehealth track record, strong leadership and partnerships, excellent patient and provider experience, and a robust, reliable, and scalable technology platform. Like any new technology, adoption takes time. However, partnering with an experienced telehealth company with robust partnerships offers a quick way to get started with virtual clinical trials. Select a focus and goals for the initial virtual trial launch and once participants and researchers understand the convenience, cost and quality improvements, they are more likely to continue using it. When thoughtfully executed, a configurable telehealth platform can allow research teams to improve the patient and provider experience, the quality of data collected, and efficiencies throughout the clinical trial process.

Pharmaceutical companies and clinical research organizations now have the chance to implement the next model of clinical trials – flexible, virtual trials that provide a real-time connection to relevant patients.

²⁹ American Well, Telehealth Index: 2017 Consumer Survey, 2017.

³⁰ Mathieu E, Barratt A, Carter SM, Jamtvedt G. Internet Trials: Participant Experiences and Perspectives. *BMC Med Res Methodol.* 2012;12:162.

About the Authors

Ray Dorsey, MD, MBA

University of Rochester Medical Center

Dr. Ray Dorsey is the David M. Levy Professor of Neurology and Director of the Center for Health + Technology at the University of Rochester. Through creative use of technology, he and his colleagues seek to enable anyone anywhere to receive care, participate in research, and benefit from therapeutic advances. Dr. Dorsey previously directed the movement disorders division and neurology telemedicine at Johns Hopkins and worked as a consultant for McKinsey & Company. His research has been published in leading medical, neurology, and economic journals and has been featured on National Public Radio, in *The New York Times*, and in *The Wall Street Journal*. In 2015, the White House recognized him as a “Champion for Change” for Parkinson’s disease.

Jeff Kosowsky, MD, PhD

American Well

Dr. Jeff Kosowsky is American Well’s Senior Vice President of Corporate Development and focuses on strategic partnerships, large investors, and M&A opportunities. Jeff brings to American Well more than 20 years of experience in healthcare, high tech, business management and consulting. Before joining American Well, he led efforts in business and clinical analytics and population health at MEDITECH. He has extensive experience in e-commerce and software services, including leadership roles at GSI Commerce and Idiom Technologies. Prior to that, Jeff was an Associate Partner at McKinsey & Company where he focused on healthcare and high-growth technologies companies. Mr. Kosowsky graduated summa cum laude from Harvard College and subsequently received a Doctorate in Applied Mathematics from Harvard University and a Medical Degree from Harvard Medical School.

Amnon Gavish, ScD

American Well

Dr. Amnon Gavish serves as Senior Vice President of Business Operations at American Well and is responsible for strategic partnerships and development of new market segments for the company’s products and services. Prior to joining American Well in December 2015, Dr. Gavish served as Senior Vice President of Vertical Solutions at Vidyio, a leading provider of software-based cloud-based video conferencing service, where he was responsible for the company’s go to market strategy in vertical markets with an emphasize on the healthcare market. He has until recently been a Director at the American Telemedicine Association and served as the Chairman of its Industry Council. Dr. Gavish holds a Doctor of Science degree in Electrical Engineering from the Technion, Israel Institute of Technology.

Abigail Arky

American Well

Abigail Arky is a Business Development Associate at American Well and is responsible for generating and qualifying Enterprise Health System leads. Abigail brings clinical experience to her role at American Well as she was a Clinical Research Associate for the Center for Health + Technology at the University of Rochester. Here she contributed to trials investigating the feasibility of telemedicine to deliver specialty care for patients with Parkinson’s disease and studies involving wearable sensor technologies to monitor the progression of neurological disorders. Abigail holds a Bachelor of Science in Biology from Hobart and William Smith Colleges.