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May 2022

The Case for Mobile Healthcare Clinics in Research Studies

**How Mobile Clinics Are Accelerating Patient
Recruitment and Screening, Boosting Retention, and
Providing Access to Diverse Patient Populations**

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Overview

Finding and enrolling the right participants in a clinical trial is no small feat. Keeping them enrolled is even harder. That's because participating in trial takes significant effort on behalf of the patient. Scheduling, traveling to, and undergoing periodic assessments means time spent away from family, obligations, and daily life. Sponsors and clinical research organizations (CROs) must find ways to reduce barriers to clinical trial participation in order to diversify their trials and keep scientific development moving forward. This white paper discusses barriers to clinical trial enrollment, retention, and diversification and how offering participants the option of having their exams conducted via mobile clinics can help reduce the burden on the participant as well as the site, ultimately increasing patient, Sponsor, CRO, and site satisfaction.



Introduction

The COVID-19 pandemic forever transformed business operations and service delivery methods, and healthcare is no exception. The days of self-isolation, travel restrictions, limited staffing, and site closures made us all realize that with today's advanced technology, we're able to accomplish more virtually than ever before. Telehealth and telemedicine became the norm rather than the exception, and while the severity of the pandemic has waned, healthcare providers continue to utilize the latest tools and technology to provide effective healthcare in a hybrid setting that's both convenient and cost-effective for patients and providers.

What's also been permanently altered is the way we conduct trials and navigate the complex landscape of health and safety of patients and site staff. In early 2020, forward-looking CROs, Sponsors, site management organizations (SMOs), and key opinion leaders (KOLs) heeded the FDA's updated guidance for added flexibility in the collection of research data.

Refusing to allow the pandemic to disrupt their clinical trials, many shifted to hybrid or decentralized models that would allow them to continue to assess the safety and efficacy of their treatments in a flexible, secure, and convenient way.

In recent months, travel restrictions have lifted and most of the limitations of the pandemic are no longer an obstacle. Clinical trial starts have rebounded to or beyond their pre-pandemic levels. Three-month moving average biological and drug Phase 3 starts are up 36%, 6%, and 16 % compared to the same metric one year, two years, and five years prior, respectively¹. Sponsors and clinical trial administrators are evaluating the ways they can address this growth now and into the future, and they're beginning to understand that there is great value in hybrid models. Let's take a look at the many crucial reasons for that, as well as why those forward-looking CROs, SMOs and KOLs who originally saw mobile clinics as a "rescue mission" during the pandemic continue to utilize them as a safe and effective way to expand the reach of traditional clinical trial sites.

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¹ *Decentralized Clinical Trials: What Are The Opportunities For Data & Cost Savings?* Clinical Leader, October 19, 2021

Traditional Trial Model Obstacles

Clinical trials have long been conducted within a centralized model wherein patients are recruited, screened, and required to attend periodic assessments at designated healthcare facilities. Although trial participation provides patients with hope and access to a promising new therapy, it warrants significant sacrifice in the form of travel and time away from their personal lives, family- and job-related obligations, and daily routines.

The High Cost of Delays

As a result, about 80 percent of delays in clinical trial timelines are accounted for by patient recruitment and retention. An estimated 85 percent of all trials will experience delays, with 94 percent being delayed by over a month. First and foremost, these delays threaten the quality of life of patients who would benefit from the potential life-changing therapies being developed by the CROs. The financial impact is also quite significant, costing between \$600,000 to \$8 million each day the trial is delayed. For a product with an estimated \$1 billion in annual revenue potential, each delayed day translates to \$2.7 million in lost revenue before patent expiration.¹

Burdensome Travel

Geography and the distance to the clinical site was cited as the main barrier to trial participation by 60% of patients who responded to CISCRP's 2021 Perceptions & Insights study, which is conducted every two years and offers the most comprehensive look to date at the ideal clinical trial experience from the global public and patient perspective. Of those patients that did participate in trials, 44% said that travel to the study clinic remains a top burden of participation, with a quarter of respondents traveling over an hour one-way for in-person clinic visits. As a result, many respondents indicated a preference for virtual visits and reduced travel time.²

Approximately **30% of patients** drop out of clinical trials, resulting in heavy financial costs. On average, it costs **\$6,533** to recruit one patient to a clinical study, and the cost of replacing patients is even higher. The average cost to recruit a new patient if one is lost due to non-compliance is **\$19,533**.³

¹ *Clinical trials and their patients: The rising costs and how to stem the loss*, Pharmafile, March 2016

² *CISCRP Perceptions and Insights Study 2021*, CISCRP, September 2021

³ *The True Cost Of Patient Drop-outs In Clinical Trials*, MD Group, October 1, 2020

Traditional Trial Model Obstacles (cont.)

Lack of Diversity

One of the three main tenets outlined in the Belmont Report of 1976 that serves as the foundation for clinical research to this day is Justice, or the fair distribution of costs and benefits to potential research participants. While it is widely agreed that clinical trials should be made up of participants that reflect real-world populations so that treatments are tested for all who may need them, there is currently – and has been historically – a lack of diversity in clinical trials.

Statistics from a panel discussion at the BIO International Convention in 2019 indicated that while racial and ethnic minorities make up 38.7% of the U.S. population, their rates of inclusion in trials range from a high of 16% to as low as 2%. African-American participation rates are lower than 5%, and Latinos make up only 1% of clinical trial participants, but 18% of the population as a whole.¹ Among the other minorities often excluded from clinical trials are people living with chronic comorbidities and pregnant women.

A critical component to maintaining diversity is ensuring that clinical trial sites are geographically accessible to all – not just those near an urban center. Key prohibitive barriers to participation can be the location or distance to trial sites, limited transportation, work, caregiving constraints, and sometimes a lack of access to technology, especially for decentralized trials that require data input and monitoring.²

In late 2020, the FDA established new guidelines to support treatment for patients of all backgrounds. Among the recommendations issued in these guidelines is for the industry to “Make Trial Participation Less Burdensome for Participants” by considering the use of mobile medical professionals to visit participants at their locations instead of requiring participants to visit distant clinical trial sites.³

Key prohibitive barriers to participation can be the location or distance to trial sites, limited transportation, work, caregiving constraints, and sometimes a lack of access to technology, especially for decentralized trials that require data input and monitoring.

¹ *As precision medicine grows, so does the importance of clinical trial diversity*, MedCityNews, July 7, 2019

² *Three key ways to drive diversity in clinical trials*, Antidote, March 30, 2022

³ *Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs*, FDA, November 2020

Reduce the Barriers to Participation, Retention, and Diversity

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Virtual visits are simply not possible in many trials due to the clinical expertise and technology required to perform the assessment and collect the patient data. For example, in ophthalmic trials developed for patients with loss of vision and diseases of the eyes, assessments involve examinations that must be performed in-person at an ophthalmologist's office utilizing high-tech vision testing equipment. Mobile clinics overcome that obstacle by bringing the assessments directly to the patient, thereby reducing the barriers associated with patient participation, retention, and diversity.

The Benefits of Decentralizing

Some regulatory and quality assurance groups are, understandably, concerned about maintaining compliance and equipment calibration within a decentralized or hybrid model. But as clinical operations and patient advocacy teams know, moving forward often requires us to challenge the status quo and think outside the box, or outside the site in this instance.

Experts say that decentralized models can provide several advantages compared to traditional clinical trials conducted solely within centralized clinical trial sites¹, including:

- Faster trial participant recruitment, which can accelerate trial participant access to important medical interventions and reduce costs for Sponsors.
- Improved trial participant retention, which may reduce missing data, shorten clinical trial timelines, and improve data interpretability.
- Greater control, convenience, and comfort for trial participants by offering at home or local patient care.
- Increased diversity of the population enrolled in clinical trials.

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¹ CTTI Recommendations: Decentralized Clinical Trials, Clinical Trials Transformation Initiative, September 2018

Reduce the Barriers to Participation, Retention, and Diversity (cont.)

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The Benefits of Decentralizing

Many stakeholders are already finding that a hybrid trial model using a combination of site-based and mobile assessments offers the flexibility participants want and trials need without sacrificing key elements such as compliance, calibration, and data quality. According to leading GCP quality and compliance solutions provider WCG Avoca's State of the Industry Report, 88 percent of CROs and Sponsors are already using or are planning to use hybrid models in their clinical trials.¹ Most respondents agreed that decentralized activities benefitted retention and diversity of study participants, as well as the streamlining of clinical development programs, including the sparing of required human resources.



¹ *The 2020 Avoca State of the Industry Report: Innovation by Fire, Diversity and the Next Normal*, WCG Avoca, June 2021

Accelerate Patient Recruiting and Screening

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An Extension of the Site

Mobile clinics acting as an extension of a trial's physical site are deployed throughout the United States to provide trial participants with the accessibility and convenience of a mobile center without sacrificing the quality of care administered. Highly qualified, friendly clinical staff perform secure, compliant, and timely data collection while delivering a safe and informed experience for participants. And with only one patient onboard at a time, staff is able to work at a pace comfortable for the individual patient.

This model helps to considerably reduce the burden on the physical site and speed the enrollment process. Staff often lack the time necessary to sift through lengthy charts or don't have the resources to batch patients by volume. Mobile clinics can see up to 30 patients a day, significantly augmenting brick and mortar sites with extra staffing to do more routine, high throughput services.

Additionally, a pre-screening program can be implemented via mobile clinics to qualify patients for and then refer them to clinical sites, further alleviating the burden on the site as well as the patients and their families. This allows the study to extend its focus to patients the sites can't normally access due to remote locations or underserved communities.

Faster Time to Market

Companies have found that incorporating mobile clinics accelerates time to submission and advancement to the next trial phase, as it increases enrollment speed and decreases screen failures as a result of the mobile clinic's ability to pre-screen patients to help qualify them for the next phase of the trial. Reducing the barriers related to travel, compliance, and ongoing participation results in a much higher retention rate, significantly reducing trial delays and ultimately allowing companies to bring therapies to market more quickly.

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Only when companies accommodate individual needs can they increase patient enrollment and keep patients engaged throughout the course of the trial.”¹



Jennifer Turcotte, Director
Global Life Sciences Industry
Salesforce

¹ *Why Decentralized Clinical Trials Are the Wave of the Future*, Salesforce – The 360 Blog, July 12, 2021

Mobile Vision Clinics in Ophthalmic Research

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Ophthalmology is one therapeutic area wherein the hybrid model has been embraced by some Sponsors during the past couple of years. State-of-the-art Mobile Vision Clinics (MVCs) were deployed throughout the country to perform the direct-to-home key follow-up assessments, enabling them to move forward with their trials even in the midst of a pandemic. The Sponsors that adopted this patient-centered approach saw the numerous benefits such a model can provide.

Replica of Exam Setting

Regulatory and quality assurance groups will gain peace of mind working with a provider like 20/20 Onsite, since its MVCs are set up to replicate the traditional assessment process. Each MVC comes staffed with a trained and knowledgeable ophthalmic technician and technology to have the assessment remotely overseen by a licensed optometrist or ophthalmologist, if required. Processes meet CDC guidelines for infection control, as staff wear proper PPE, the vehicles are upgraded with advanced 3-stage HEPA air filtration, and the exam area is sterilized between patients. And finally, the mobile clinics are outfitted with dimmable lighting, clean and organized data systems as well as the same high-tech vision testing equipment utilized at traditional brick-and-mortar sites.



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Mobile Vision Clinics in Ophthalmic Research (cont.)

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Quality of Data

20/20 Onsite recently completed an observational study to assess how the results of eye exams conducted in mobile settings compare to those conducted in traditional in-office settings. The study analyzed the quality of subjective refraction, autorefraction, and keratometry measurements in a mobile eye setting and found no statistically significant difference between data retrieved in the mobile vision clinic setting as compared to data retrieved through an in-office exam¹. The indication that mobile eye evaluations produce results that are just as accurate as in-office examinations validates mobile optometry as a delivery system for reliable, repeatable, and accurate eye care that can benefit patients across the country who need specialty vision service closer to home, either routinely or in clinical research studies. The results from this study enhance the company's mission to improve access to high-quality eye exams for individuals living in geographically disparate areas in need of equitable care.



This observational study tells us that mobile eye evaluations produce results that are just as accurate as an in-office examination. This study not only highlights the caliber of the machines on the mobile clinics, but also the years of experience and innovation it takes to obtain high-quality data as we provide care across the country."



Debi Sarma, OD
Optometrist and Principal Investigator
20/20 Onsite

¹ 2020 Onsite Completes Observational Study that Confirms Eye Exams in Mobile Settings Have Same Results as In-Office Exams, Business Wire, August 19, 2021

Mobile Vision Clinics in Ophthalmic Research (cont.)

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Success Story Spotlight

Prior to the pandemic, clinical-stage biotechnology company AGTC (Applied Genetic Technologies Corporation) began conducting clinical trials for two ophthalmic diseases. Faced with the nationwide shutdown in March 2020, most of the trials' participants were unable appear for their scheduled follow-up assessments. Without accurate and timely data derived from these ocular assessments, the trials would've been significantly delayed. AGTC partnered with 20/20 Onsite to perform direct-to-home key follow-up assessments, permitting them to move forward with the XLRP and ACHM trials.

AGTC met its goal of reporting out data from all three ongoing clinical trials in the fourth quarter of 2020. As of March 2022, AGTC completed 232 assessments over 48 states across five trials. Since the MVCs removed most of the barriers related to travel, compliance, and ongoing participation, the trials had a much higher retention rate. The use of MVCs in these clinical trials resulted in faster time to market and decreased costs. Many patients found the MVC experience to be compatible with that of the traditional setting. Some, particularly the pediatric populations, even preferred the MVC experience, with 97 percent of participants saying they would recommend the service. What began as a pandemic contingency plan has blossomed into much more, and AGTC and 20/20 Onsite have expanded services beyond pandemic rescue into additional studies.

Since the **MVCs removed most of the barriers** related to travel, compliance, and ongoing participation, the trials had a much higher retention rate. The use of **MVCs** in these clinical trials resulted in a high patient satisfaction rate, **faster time to market, and decreased costs.**

Leverage the Acceleration, Predictability and Efficiency of a Mobile Clinic

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Partnering early with a mobile healthcare provider will afford the flexibility patients look for in a trial. You can make your trial accessible to more diverse populations by offering participants a choice of appearing for their assessments either at a designated site or by taking your trial directly to those who do not have the ability or desire to travel to a site. Additionally, mobile clinics can provide temporary expanded capacity to sites when needed. Developing standards of practice (SOP) early in the partnership will ensure clarity of roles and allow the team to focus on providing exceptional care to the patient.

Choose the Right Mobile Partner

CROs, Sponsors, and KOLs should seek providers that staff their mobile clinics with pre-screened, licensed healthcare providers and experienced customer success team members. The provider should offer customization of their mobile clinics with specialty equipment based on the individual study's needs. This includes the same leading-edge technology utilized at brick-and-mortar sites.

Finding the right partner with the right experience requires careful vetting. Be sure to get answers to these questions as you interview potential mobile healthcare providers:

1. What processes, procedures, and training does the mobile provider have in place to maintain compliance with your protocol?
2. Is the mobile provider compliant with individual state licensure requirements?
3. Does the provider require human subject protections training and embrace Good Clinical Practice?
4. Does the provider deliver source data that is attributable, legible, contemporaneous, original, and accurate?
5. In what ways does the provider prioritize data security?
6. How does the provider ensure the quality and integrity of their data?
7. Does the provider prioritize staff diversity?
8. Can the provider pre-screen patients before they reach the clinical site to ensure they are qualified to participate and positively impact costs like enrollment speed and screen failures?
9. Can the provider offer proof that patients have been satisfied with the quality of care they received on their mobile clinics?

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Conclusion

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Decentralized and hybrid clinical trial models are gaining traction among companies worldwide for certain studies that would benefit from the flexibility and convenience they provide. Those organizations that are already utilizing mobile clinics have seen their ability to reduce the barriers to participation, retention, and diversity, thereby accelerating patient recruitment and screening processes, reducing trial delays, and getting therapies to market more quickly.

20/20 Onsite is an adaptable partner quickly evolving as a patient-centric care leader that can help you execute your transition to a hybrid or decentralized trial. Today's complex regulatory processes require a partner like 20/20 Onsite who understands these complexities and can pivot quickly when regulations change. From doing routine eye exams to strategizing to recruit, screen, and enroll the right trial participants, to performing simple to complex assessments, 20/20 Onsite can help you take your trial to the next level. For more information about the convenience and flexibility of mobile vision services, contact **20/20 Onsite** today at lifesciences@2020onsite.com.

