Bringing Clinical Trials To Everyone's Backyard

By Medical Research Network

Supporting Diversity In Clinical Trials

While *Patient Diversification* is the new phrase being touted across clinical research, the tools, models, and means to achieve this have been around for almost two decades. Those working in the industry know that most patients in clinical trials are still white and male. While **people of color** make up approximately **39% of the population of the US**, they only represent between **2 and 16% of patients in clinical trials**.[1]

How can we better support and provide access to the patient groups that are underrepresented in the clinical research space to make participation a real option for their healthcare?

Utilizing community-based trial models along with mobile technology, supporting and strengthening research sites, and working together with all stakeholders can achieve this objective. Through decentralized clinical trial (DCT) tools and models we can increase patient reach, improve recruitment and retention, and reduce timelines and costs of trials.

But how do you use decentralized elements correctly? And do they really make a difference?

There are several elements that can be tailored and combined to create a truly decentralized trial, bringing clinical trials to any patient, any community around the world.
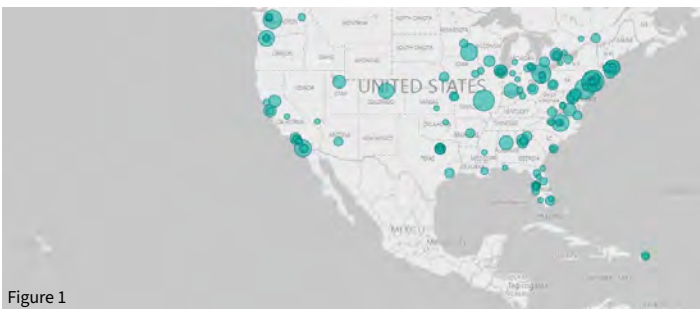
Community-based Clinical Trial Visits

Community-based, clinical trial visits are designed to bring trials to those who find it inconvenient to participate in the traditional clinical trial model at a hospital site. The burden of traditional trial visits reaches further than just the patient's time while participating. Organizing their travel, scheduling time off from work, childcare, as well as the expense of traveling, the time that lengthy site visits can take, all on top of potential mobility or cognitive challenges that a patient may have as a condition of their disease, makes clinical trials impossible or too inconvenient for many.
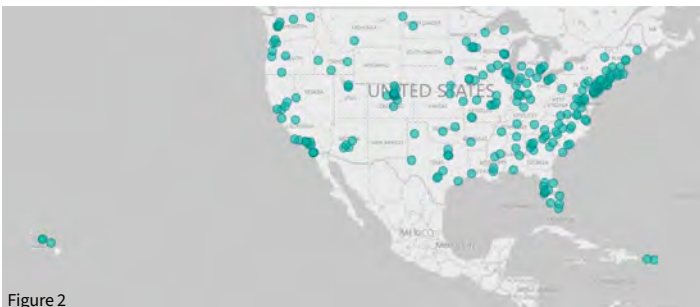
Healthcare Professionals (HCPs) going to the patient, to conduct clinical trial visits outside of the site, in their home, school or place of work, increases flexibility for the patient and removes some of those burdens and barriers.

Importantly for Sponsors and Sites, community-based clinical trial visits also increase the geographic reach for patient recruitment. This method can work to serve a greater number of patients from a greater number of communities. Participants don't always live near a site or want to travel to a site, solutions like Home Trial Support can bring the trial to them.

Sample of 5,000 adults, median distance willing to travel for routine care visits[2]

All Adults	**20.4**	**miles**
Age 65+	**18.1**	**miles**
Hispanic Origin	**17.9**	**miles**
Urban Resident	**17.6**	**miles**

An analysis of 318 patients MRN has supported[3] in their clinical trial journey showed the **median distance we were able to reach them was 64 miles** from their site.

This is more than **3x** the distance patients are reporting they are willing to travel for routine care.

Over **54% of these patients lived 125 - 620+ miles away** from site their research site.

Site Location

Figure 1

Healthcare Professional Location

Figure 2

Community-based models, like Home Trial Support, identifies a qualified healthcare professional within one hour's driving distance from the patient (with the exception of the MRN travel nurse model, not shown here).

The research sites MRN has supported[3] over the last 12-months is shown in Figure 1. The diameter of each bubble is weighted by the number of patients we have delivered care to for each site.

Local healthcare professionals identified to deliver care is shown in Figure 2. A solution like Home Trial Support can extend a site's reach well beyond the distance a participant may be willing or able to travel.

Not only does this approach increase geographical reach it also supports further patient flexibility as we see with **12% of our visits taking place outside of standard clinic hours.**

eClinical

There are several different tools covering delivery of clinical research visits through technology.

- Telemedicine – connecting physicians with their patients using a video link remotely (eg. on a mobile device or computer)
- eConsent – tools designed to fully inform patients about the trial, allowing them to consent and or reconsent to participation remotely.
- ePRO or eCOA – digital devices designed for patients to remotely collect their own data and transfer that data to the site.
- eSource – direct data capture wherever the patient is by a healthcare professional, using a remote device.

Statistics show that there are now 7.2 billion smartphone users in the world today - that is 90% of the worlds population[4].

In the United States alone 81.6% of the 338.29M population own a smartphone but we also know that smartphone and mobile phone penetration is closely related to demographic affluence – the wealthier the population, the more prevalent the technology.[4]

Telemedicine has increasingly become a key method to access care, but in every country surveyed, better educated and higher income people are more likely to use the Internet than people with lower levels of income or education.[4,5]

For the other e-clinical tools, smartphones represent the main access device, yet we know there are significant differences in Smartphone ownership based on age, education level obtained, yearly earning and geographic location, all the demographics that pharmaceutical companies want to encourage to participate, so technology can't be the only decentralized element employed if we truly want to diversify the population of patients taking part in clinical research.

% of US adults who own a smartphone[4]

Household Income

Less than $30K	$75K or more
67%	**93%**

Educational Attainment

Less than highschool	College or higher
57%	**91%**

Community Type

Rural	Surburban	Urban
65%	**78%**	**83%**

Technology can clearly expand the patients that we're able to support but it isn't the universal leveler that many tech only DCT providers would have you believe – decentralizing a trial means bringing the care of the patient to their own community. **It's the combination of in-home clinical delivery supported by technology that makes this successful.**

Site Success

Sites are key for successful patient support and clinical trial delivery. Patients still need a clinical team, primary physician, and the facilities that only a clinical site can provide even when they elect to have some visits delivered at their home. So how do we support Sites to success, and can we look at Sites in another way?

Approximately **88.9% of the US population lives within 5 miles of a community pharmacy** – this includes chains, government pharmacies, independent pharmacies and regional franchises.[6] In **rural areas approximately 76.5% of these pharmacies are franchises or independent**.[6]

What if we went into those communities to conduct clinical research – increasing the clinical spaces that patients have access to, rather than limiting them.

Clinical research delivery comes with a complex set of challenges for already overworked and under resourced sites. Sites have lost significant numbers of staff since the pandemic, leaving them under resourced to deliver their patients healthcare needs, before clinical research participation can even be considered.

Many sites don't have the time or capacity to support clinical research which limits the patients that can be considered for these trials.

Sites need expert support to enable them to deliver the increasingly complex protocol requirements of clinical research while allowing them to generate a meaningful income.

If sites can't participate, their patients aren't offered the opportunity to participate which is a lose, lose for everyone.

We have provided site specific support on over 128 studies across the globe, with everything from administrative support, clinic resourcing, patient recruitment all the way to providing a site with everything they need to successfully deliver clinical research.

37%
of sites under-enroll [7]

11%
fail to recruit a single study [7]

On average, clinical trials overrun by
15% [7]

Sites, community visits and technology, that's got to be everything we can do, right?

True Patient-centricity

The biggest unaddressed challenge for many global communities is the deep mistrust that comes from years of mistreatment at the hands of clinical research.

Black and brown patients don't get the same support and acknowledgment as white counterparts in a healthcare setting, with historic atrocities such as the Tuskegee study or the controversial way HeLa cells were obtained without consent, through to the current disparity in maternal mortality rates between white and black mothers, to name only a few.

Clinical research is still a predominantly white space, it hasn't been built with global patients in mind, and as with any white space there are conscious and unconscious biases regarding race, and ethnicity that need to be confronted and resolved.

In **2019 54.6% non-Hispanic Black adults across the US had experienced racial / ethnic discrimination in healthcare**[8] and the 2019 COVID pandemic was a stark reminder of this, with many black patients choosing not to vaccinate or seek medical support due to the aggression, disregard and lack of compassion they have faced previously.

So how do we open up clinical research to patients from within these communities?

- **We prove they can trust the medical community.** We reach out with openness and transparency, we address the atrocities, and we show what is being done to remove racial discrimination from this space.

- Only **5.7% of U.S Physicians are black**,[9] so most physicians creating protocols don't fit the demographic of patients they are trying to engage with. We need to **engage black physicians and black patients** in order to create protocols that work for them.

- eSource – direct data capture wherever the patient is by a healthcare professional, using a remote device.

> Re-addressing the cultural disparity isn't something that will happen overnight, but **continuous steps in the right direction and is what's needed.**

Conclusion

Advances in medical technology, delivering clinical trial visits in patients own communities, supporting sites to success and addressing patient diversity and centricity, it's a heavy task but one that is important to bring about a real difference for all patients.

Reducing the burden of participation for patients is at the core of what we do, we're passionate about delivering clinical trials in the best way for the patients that we serve, making their lives a little easier and moving medicine forward in the process.

We all need to make a difference in patient population diversification but without clear action and accountability, diversification becomes just another buzz word.

We'd love to support you with your next clinical trial, and make sure all patients are given the best chance to participate, because we really do believe in bringing clinical trials to everyone's backyard.

About MRN

MRN provides a gold standard platform of clinical trial services designed to work together in synergy; bringing trials closer to patients, making trials faster, more efficient, more inclusive and more accessible for all patients and for all research sites around the world.

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