Driving Diversification & Reach With Technology In Community Decentralized Clinical Trials

By Medical Research Network

One of the greatest challenges facing the clinical trial landscape is one that is still needs attention and discussion – inclusivity through diversity. Diversity in clinical trials is critical for the development of safe and inclusive new medicines and therapies.

What do we mean by "safe and inclusive" – aren't all medications that are approved exactly that? The short answer is…not always. It has only in recent years that diversity in clinical trials has become a requirement that the FDA, and health authorities globally, expect clinical study researchers to adhere to.[1,2]

This has meant that some drugs have been approved without the researchers fully understanding how effective, or even harmful it may be in different genders, ages, and races. This can be costly for drug developer when drugs that have been approved for broad spectrum uses are either limited or recalled completely.[3]

Further it is not only those drugs that have been developed and approved that have been flagged for lacking representative data, but also those in clinical trial stages. A recent example is from the Covid-19 pandemic, where Moderna had to slow down it's trial in order to increase the number of participants of color from 7% to 13% in order for cohort populations to be representative of the African American US population.[4,5]

So, the big question, how do we start overcoming these barriers, and begin enrolling diverse, representative participant cohorts in clinical trials?

Community-based, Decentralized Clinical Trial Solutions

It starts with taking trials into diverse patient communities, instead of expecting the patients to find and then commit to trials that are not local to them. This is done through Decentralized Clinical Trials (DCTs) that focus on community-based solutions. These community-based DCT models can enable an increase in patient reach, improve recruitment and retention, and help keep trials on time and within budget.

One of the fastest ways to find community sites and start reaching different populations groups is by working with a Site Network.

Site Network's will connect your trial with local sites that are not only supported by the network to effectively and efficiently run the trial but are made-up of Principal Investigators (PIs) and study teams who understand the needs and challenges faced by their local community.

However, there are still those participants who don't always live near a site or have the ability to travel to a site (community-based or not), solutions like Home Trial Support can bring the trial to them. This means Home Healthcare Professionals (HCPs) travel to the patient, wherever is most convenient for the patient outside of the site. It does still depend on suitability, but essentially, these visits can take place in the patient's home, school or place of work.

While both Site Networks and Home Trial Support (HTS) provide compelling solutions to not only finding diverse patient populations to enroll, but also removing the barriers to the participation, there is an almost obvious way to reach patients no matter where they live – through technology.

Technology has great potential to reach both more patients and more community sites, especially when you consider that 81.6% of the population of the US are actively using a smartphone and it is predicted that 72% of internet users will exclusively use mobile devices to access the internet this year. [6]

Technology In The Community

Of course, there is the question of who actually has access to a smartphone (and can use it effectively). While the latter is really individual-dependent, this first one is easy: [6]

- Over 70% of users are 18 -64 years old.
- On average, 75% of the US population living in urban, suburban and rural areas are smartphone users.
- 76.3% of smartphone owners are White, Hispanic and African American.

What this tells us is there's another way of reaching diverse population groups, regardless of their location, background, age or ethnicity, and that the reach of mobile devices and technology, and the role they can play in conducting clinical trials, should be considered when it comes to community DCTs.

Clinical Trials & Technology

eClinical technology, combined with mobile devices, can be used in a number of ways, across multiple DCT solutions to provide remote access, for sites and patients, to clinical trials.

Systems and digital tools, such as ePRO (Electronic Patient-Reported Outcomes) or eCOA (Electronic Clinical Outcome Assessment) can be used on digital devices and are designed for patients to remotely collect their own data and transfer it to sites.

While eConsent tools are designed to fully inform patients about the trial, allowing them to consent and reconsent to participation remotely.

The use of technologies like this has numerous pros, especially when reaching those in remote locations, but what we've found is there can be issues when technology is used exclusively. Some of the most common issues that arise are:

Human Error

The successful approval of clinical trials relies on the quality of data submitted. As with anything, when humans are required to do something there is always room for error – no matter how marginal.

With self-reporting there is always the risk that information may not be saved correctly by the patient/their carer.

It also comes down to how complex and user-friendly the digital device/app is and how experienced the user is. What may be "simple" to some is far more complex to others, and that can lead to mistakes that impact the quality of the data, or even the loss of data –which may not always be retrievable.

Technology Failure

There are times when you can do everything right – as software engineer designer to make something as user-friendly as possible, and as a user who is confident in what they are doing, when tech just fails.

While some may be able to resolve the issues, there can be those software bugs that are more difficult to remotely manage, even with the help of a remote technician.

The knock-on effects of a technology failure can range from minor, where data has to be retroactively submitted, to more severe, with patients getting frustrated as their time and energy is spent (sometimes repeatedly) trying to resolve issues.

If the issue(s) are not easily resolvable, this can lead to either the patient choosing to drop out from the trial or having to drop them from the trial due to insufficient data collected over a period of time.

Technology & The Human Touch

Sometimes it is the marriage of solutions that provide a truly optimized result. By pairing other DCT solutions, such as HTS or site networks, with technology it is possible to design a trial that still has the reach required to enable patients in community settings to participate.

HTS HCPs are able to help patients digitally submit information or even submit it for them. The HCPs themselves are able to use technology to submit eVRFs (Electronic Visit Report Forms) after seeing a patient in their home.

Sites in a supported Site Network are also able to use technology to connect with patients, either through remote check-ins via video-calling or through monitoring of the information shared with the patient through various devices and tools. Sites are also able to review HTS HCP data, once it has been submitted through the eVRF.

Technology and digital devices offer infinite possibilities when it comes to connecting patients and clinical trials, engaging patients, streamlining data collection, and can be a powerful tool in driving diversification in community-based, DCT clinical trials.

MRN's technology tools are integrated across all our solutions, making seamless collaborations possible for our Sponsor Sites, HST HCPs and MRN Network Sites to reach patients, collaborate and capture high-quality, optimized data from any community in any location.

Learn more about our community-based, technology powered DCT solutions here: https://themrn.io/solutions/

References

1. Food & Drug Administration (FDA). *Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry*, Nov 2020, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-p opulations-eligibility-criteria-enrollment-practices-and-t rial, Last Accessed Jan 2025.

2. Vidal L, et al. E*quitable inclusion of diverse populations in oncology clinical trials: deterrents and drivers*, ESMO Open, Vol 9 Issue 5, May 2024.

3. Bibbins-Domingo K, et al. *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups*. May 2022, https://www.ncbi.nlm.nih.gov/books/NBK584396/, Last Accessed Jan 2025.

4. McCarthy A. *Embracing Diversity: The Imperative for Inclusive Clinical Trials*, Trends in Medicine, Harvard Medical School, Jun 2023. https://postgraduateeducation.hms.harvard.edu/trends-medicine/embracing-diversity-imperative-inclusive-clini cal-trials, Last Accessed Jan 2025.

5. *Steenhuysen J. Exclusive: Moderna vaccine trial contractors fail to enroll enough minorities, prompting slowdown*, Reuters, Oct 2020. https://www.reuters.com/article/us-health-coronavirus-v accine-moderna-ex/exclusive-moderna-vaccine-trial-con tractors-fail-to-enroll-enough-minorities-prompting-slow down-sources-idUSKBN26R1SP/ Last Accessed Jan 2025.

6. Howarth J. *How Many People Own Smartphones? (2024-2029)*, Jun 2024. https://explodingtopics.com/blog/smartphone-stats/Last Accessed Jan 2025.

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.

Our Offices

UK
Medical Research Network
Ltd Milton Keynes
+44 (0)1908 261 153

USA
Medical Research Network Inc.
Chicago
+1 (847) 779 7857

Spain
Medical Research Network
Spain, Sociedad Limitada
Madrid
+34 640 365 683

Germany
Medical Research Network
Germany, GmbH
Industriestrasse Stuttgart-Vaihingen
+49 (0)178 8088 618

France
Medical Research Network
France, Lyon
+34 640 365 683

Japan
Medical Research Network
Japan KK, Tokyo
+81 (0)3 5322 2860

enquiries@themrn.co.uk
www.themrn.io