The Big Picture

Diversity in Clinical Trials

Executive summary

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1. On average, 20% of patients drop out of clinical trials.
2. Up to 50% of sites fail to recruit enough patients.

Failing to recruit and retain patients results in **86% of all trials not meeting their enrollment deadlines** and **30% of Phase III trials fail** – ultimately driving up costs and risk.

Considering **only 8.1% of potential patients enroll,**[1] with an average of 20% of patients dropping out[2] of clinical trials, and the **average cost of running a Phase III clinical trial sitting at $55,716 a day,**[2] the financial significance of not recruiting and retaining patients becomes quite stark. Even more so when considering the average cost does not include the indirect costs of running a trial, such as the sponsor's own personnel compensation and operating and infrastructure costs.

Every day lost due to failure in recruitment and retention of patients incurs a cost – and one that may not always be retrievable.

Why are patients not enrolling and why are they dropping out?

20%

The average number of patients that drop out of clinical trials

The biggest reason patients don't enroll is there are no trials available, in fact, **approximately 55.6% of patients reported being treated where there were no trials available.**[1]

Additionally, the burden of frequent clinic visits is the most given response of why patients drop out.[1]

It is important to understand and acknowledge that this burden is not just limited to travel, but also time spent during travel and at the clinic, and the subsequent cost of travel / childcare / loss of income and stress of balancing work, family and personal obligations in order to participate. All of these challenges are exacerbated by the potential mobility or cognitive challenges that a patient may have as a condition of their disease, making clinical trials impossible or too inconvenient for many.

FDA guidance has outlined the importance of clinical trial populations reflecting the age, race/ethnicity and sex/gender distribution of the patient population with the relevant disease when assessing the risk / benefit balance for each individual patient based on the generalizability and representativeness of the clinical results observed.[3,4]

50%

Of sites are failing to recruit enough patients

Simply put, the patients that participate in clinical trials should be representative of the population that will receive the approved, marketed drug.[5] If insufficient data is provided, approvals and indications may be restricted to the population demographic of the study.[5,6]

By not considering or ignoring the issues that patients face can be catastrophic for studies. Not only is there a remarkably high risk of failing to capture safety and efficacy data, but it is also likely there will be a reduction in the generalizability of research findings. The result? Treatment limited or not offered to underrepresented population groups and directly contributing to health inequality and inequity, as well as a possibility of restricted / no approval from Health Authorities globally.[3,6]

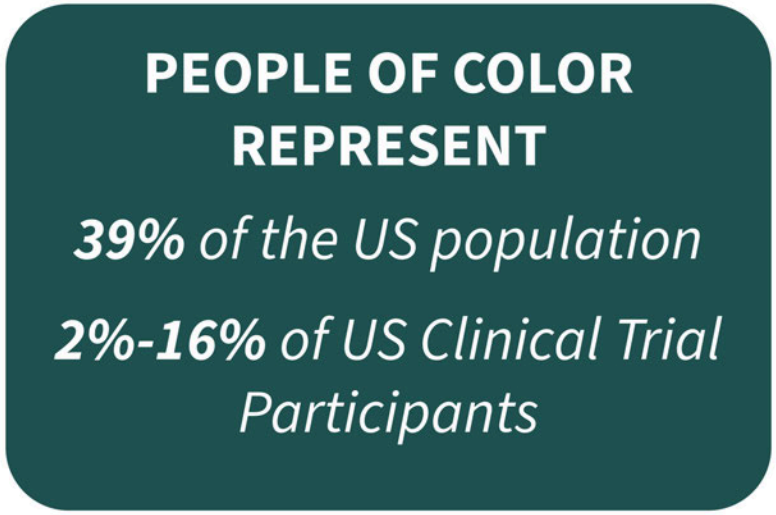
The financial implications of sponsors failing to recruit and retain clinical trial patients, along with the financial risk and ethical questionability for not ensuring diversity within their study population pool is monumental. It is also avoidable.

The most efficient solution? Bringing trials to the patients. This is achieved by stepping away from the hamstrung traditional methods of running clinical trials and pursuing alternative approaches to clinical trial design.

An Industry-wide Challenge

Enrolling Diverse Patient Populations

The industry challenge is enrolling from diverse patient populations



While diversity in clinical trial patient populations has been signed into law (in the US) under The Food and Drug Omnibus Reform Act (FDORA), it does not mean clinical trials are suddenly enrolling diverse patient cohorts, even though 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 majority, 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.[7]

When over a third of a country's population is not equally represented in clinical research, it demands an examination of the blockers causing this and discussion of solutions.

Blocker 1: Inflexible Trial Models

Traditional clinical trial models follow a simple pattern when it comes to patient enrollment from a sponsor's perspective; site selection, SIV....and then an expectation for a site to start enrolling. The realization that a site is unable to enroll the promised number of patients is then met with often-futile traditional attempts to help the site boost enrollment. Lunch and Learns, Dr-to-Dr letters, patient videos and brochures are all distributed with the hope that it will turn the tables.

When these efforts fail to sufficiently boost enrollment rates, sponsors are then left with the tasks of finding more sites, making protocol amendments and facing ever-spiraling costs. **Just a single protocol amendment is estimated to set trials back by up to 3-months** and half a million dollars in direct costs.[8]

At the very heart of this blocker is the lack of consideration for patients and their caregivers.

By continuing to follow this path, not only is clinical research delayed at great financial cost, but also at the cost of patients. Furthermore, by not adapting to the needs of potential patients and bringing more trials into communities, an unfair playing field is created – diminishing the opportunities for more patients to participate and receive healthcare.

Blocker 2: Reusing The Same Sites

Reusing the same site for your clinical trials has its advantages. From an operational standpoint, you can practically hit the ground running by reusing existing contractual documentation and study teams. Plus, there is already an existing relationship with the site.[9]

On paper, it all makes perfect sense, however, the likelihood of gathering more representative data is diminished as you're working with the same population set again.

There is a reason that the same, white, older male population is the most enrolled cohort onto clinical trials. The same sites are repeatedly used, and therefore the results are the same.

This is even reflected in past guidance encouraging the use of sites that have a history of doing the same type of study, in the same indications. It's how the situation has been created.

To move away from the past predicting the future, there is a need to change the approach to site selection - working with those community-level sites that have been trained and have the support required to take on a new study type.

The initial study set-up will be longer, but **the diversification and generalizability of the study is likely to be much improved.**

Blocker 3: Static Sites Creating Patient Burden

One of the most cited reasons for a patient withdrawing from a study is time. Travel time to and from sites, lengthy waiting times for procedures done at sites, and the time lost due to frequency of visits.

This time loss translates directly to financial loss – the inability to work during those hours, the cost of child and elder-care, the cost of travel. And if a carer, usually a family member, is required to attend these visits as well, it can double the probable financial and time cost and add strain to an already difficult time.

While it has become more common for clinical trials to offer reasonable reimbursement to participants for travel and other participation-related costs, the same cannot be said of reimbursement for the caregivers of clinical trial participants, despite them often being the reason that potential patients can join the study.[10]

By not creating **patient-centric study designs that also keep caregivers in mind**, trials will continue to experience enrollment and retention challenges.

Solutions: a new approach is needed

Simply put, there needs to be a complete paradigm shift in the way clinical trials are designed and executed.

It starts with returning to the very first question when it comes to creating a study design – who is going to benefit from this research? Once the patient is brought back to the forefront, addressing these industry-related blockers becomes easier, in theory, to do.

Solution 1: Embracing a New Approach – Decentralized / Hybrid Study Design

Inflexible trials are no longer capable of providing representative patient data due to their locations and limited understanding of the support patients and their caregivers need in order to participate.

The FDA recognizes this and has continually advised that a Decentralized approach is needed to bring clinical trials to a more diverse population group. Utilizing community-based trial models along with technology is key to this approach.

Considering **81.6% of the US population is actively using a smartphone and it is predicted that 72% of internet users will exclusively use mobile devices to access the internet by 2025**,[11] it is imperative to assess how technology can be leveraged to increase geographical reach and enable potential patients from underserved communities to participate in trials from their homes.

Additionally supporting and strengthening research sites, embracing HCP home-visit solutions and collaborating with stakeholders right at the start of the trial all enables the flexibility needed to execute a successful decentralized clinical trial (DCT).

It is through the well-executed use of DCT tools and models we can increase patient reach, improve recruitment and retention, and reduce timelines and costs of trials.

Solution 2: Site Diversification = Population Diversification

This is applicable to both the sites used and site staff.
Recent research conducted by the Tufts Center for the Study of Drug Development at Tufts University School of Medicine[12] found that **a key factor in enrolling diverse patients is having higher racial and ethnic diversity in the staff working at the investigative site.** It was also noted that private sector sites reflected greater diversity in their teams, with almost half made-up of minority groups, than those at academic centers and hospitals – where only one third of staff were part of a minority.

By using a **network of private sector and academic sites and hospitals it is more likely that your trial will include a diverse population.** And by carefully selecting private sites in and near to communities with racial and ethnic minority representations, that also reflect those they are treating will help break down barriers and encourage enrollment.

Solution 3: Make Trials More Convenient for Patients and Their Caregivers

By truly considering the needs of the patient and considering the burden placed upon them and their family, it **becomes clear that there cannot be no one-size fits all.**[13]

Solutions like Home Trial Support, where Healthcare Professionals go to the patient to conduct clinical trial visits outside of the site, allows for much **greater flexibility and an opportunity to tailor-make the visit schedule fit around the patient** instead of the other way around. This allows patients to be seen in their home, school or place of work, and removes some of those burdens and barriers.

Alternatively, by identifying and working with sites that are already part of communities, **geographical reach will increase and the burden on the patient is substantially lessened.** They are more likely to be willing to visit those sites that they are either already familiar with or at the very least are close to their home / work / school. This method can work to serve a greater number of patients from a greater number of communities.

Next Steps

Driving Diversity & Inclusion

Next Steps to Drive Diversity & Inclusion

By understanding and addressing the challenges to patient enrollment and retention we can begin to recognize the clear need for a diverse and inclusive patient population participating in clinical trials.

The next step is to then dive deeper into understanding what do we truly mean by a 'diverse' population, then understanding the gaps to serving them why. This will allow us to achieve true representation in clinical studies and research.

What are the societal gaps for serving a truly diverse patient population?

As we look at the bigger picture and begin to understand what it may take to enroll and retain patients that represent real world populations, we also need to understand what a truly diverse and inclusive patient population looks like, and the challenges they face.

While initial responses to **'what is diversity' tend to focus on race / ethnicity / gender, upon further examination you will see it goes much deeper than that.** There are several sets of defining demographic characteristics that, individually or in combinations, create a truly diverse and inclusive population.

These include demographic characteristics such as: age, culture and religion, socioeconomic status, education levels, existing illness, environment – to name just a few.[14]

While understanding these characteristics and how they can influence the ability to participate in clinical trials, it is also important to understand how they can be situationally compounded, making it even harder.[15]

With this in mind, we can begin to examine the gaps that prevent or severely limit the ability to enroll a diverse patient population.

Societal Compounding Factors

One of the biggest challenges identified by patients was the logistics and time involved when it comes to participating in clinical research. For those with kidney disease, Multiple Sclerosis (MS), or allergy/ asthma, this was a top consideration when it came to agreeing to participate than for those with other diseases.[13]

This consideration is even more **critical to those who are not close to sites, especially those from diverse patient populations.**

We reviewed a study of 5000 US adults. The study found that adult patients and/or caregivers were unwilling/unable to travel more than a median distance of 20. 4 miles to attend routine care visits. That median distance then dropped to 18.1 miles for those over 65, then again to 17.9 miles for those of Hispanic origin, and yet again to 17.6 miles for urban residents.[16]

So, what does this mean?

Well, for those that work several jobs or do not have the flexibility to take time off, and/or have elder- and child-care responsibilities, and/or may have existing health issues that are exacerbates if travel is involved, and/or...**we start to see the bigger picture – logistics and time are compounding factors that can create real challenges** - then we throw distance into the mix and for those that fit into and are impacted by the aforementioned demographic categories, it starts to look even more impossible to participate.

Considering the above, socioeconomic characteristics also really stand out – **participating in a clinical trial can be costly, even when subsidized. The situations of elder/childcare, time off work all come with costs. Then there are things such as the cost of travel and health insurance (or lack of)** – they all add up rapidly, and it compounds yet again when we consider those in racial and ethnic minorities.

By reviewing clinical trial participant feedback and aligning it with a more nuanced understanding of the key characteristics of a diverse and inclusive patient population, it becomes possible to start addressing the gaps preventing them from participating: logistics, time, costs and distance.

Lack of Trust in Healthcare

However, there is another gap to participation that is less obvious and less likely to be voiced by patients clearly is the deep mistrust that comes from years of mistreatment at the hands of clinical research. 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 and infant mortality rates between white and black mothers and their babies, **it is clear that patients of color have not, and still don't get the same support and acknowledgment as white counterparts in a healthcare setting.**

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

72%

Experience Discrimination More Than Once

A 2019 (pre-COVID) survey revealed that **21.9% of Hispanic adults and 54.6% non-Hispanic Black adults across the US had experienced racial / ethnic discrimination** and 72% of those who had been discriminated against experienced it more than once. The 2019 COVID pandemic then highlighted this, with many black patients choosing not to vaccinate or seek medical support due to the aggression, disregard and lack of compassion they had previously, and repeatedly faced.[17]

So, how do we address both the identifiable gaps and those which are the result of fear & mistrust?

A large part of that is accepting they exist. Then it comes down to working with sites, patients and communities to find the right solution for the trial / research they wish to participate in and making it easier for more patients, with an emphasis on those within a diverse population group, to enroll and remain on the trial until completion.

And we already have the solution – considering the patient population cohorts needed to deliver accurate real-world evidence that the investigative medicinal product (IMP) is suitable for those it is intended to treat.

By utilizing **community-based trial models along with mobile technology, supporting and strengthening research sites, and working together** with all stakeholders we can achieve this objective. Community-based clinical trials enable us to increase patient reach, improve recruitment and retention and improve access to local healthcare providers for local patients.

Build community-based trials, focused on patients

Patient-centric, Community Trials

Armed with an understanding of industry blockers to patient enrollment and retention, as well as a clearer, fuller view on what is meant by a "diverse & inclusive" patient population **we can start to build the bridges required to close gaps in clinical trial participation.** Transforming the delicate ecosystem of clinical trial research into a sustainable one.

Diversification & Reach Through: *Site Networks*

Site selection can be key to the success of a clinical trial.[12] Without them, conducting the incredibly intricate and elegant trials needed to make groundbreaking changes across therapeutic areas would be impossible. **Clinical research delivery also comes with a complex set of challenges that, for already overworked and under resourced sites (thanks to record numbers of staff leaving medicine post-COVID), is not a feasible undertaking.** Many are struggling when comes to delivering on their patients' healthcare needs, let alone being able to consider clinical research participation.

With sites lacking the time or capacity to support clinical research, the patients that can be considered for these trials become severely limited. For those clinical studies that have been designed with this in mind, **the use of a supported site network allows them to engage with a more diverse range of study sites,** especially those that may have been considered ineligible due to lack of experience and / or resources.

When we consider that approximately **88.9% of the US population lives within 5 miles of a community pharmacy** – including chains, government pharmacies, independent pharmacies and regional franchises, with **76.5% of these pharmacies are franchises or independent in rural areas**[18] - it becomes clear that by going into those communities to conduct clinical research we'll be increasing the clinical spaces that patients have access to, rather than limiting them.

MRN's site network allows for the engagement of trial naïve sites – those which have limited or no experience in running clinical trials – as well as sites that require additional resources.

The service can **provide expert support** which enables these site types to successfully run clinical trials and deliver on the increasingly complex protocol requirements of clinical research.

By engaging trial naïve and under resourced sites in new communities, there is an opportunity to support patients that live in different communities and require a site closer to home.

Further, working with **local healthcare providers may serve to build more trust in healthcare and research, especially when working with those who are representative of the community's demographic.** Being able to work with PIs and study teams who understand the needs and challenges faced by their local community, they will be better placed to reassure and support their patients.[12]

MRN's Site Network is growing rapidly - expanding to 100+ sites across North America, the UK and Europe in 2024. We work around the world with ease - by using our own teams of professionals supplemented with long-term and valued partners, we act as a single, centrally managed provider with delivering locally on a global scale.

Our International Development office and Vendor Management team are constantly looking for new ways to expand our services and deliver trials to patients while maintaining our high level of standardization and quality.

Participants 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.

Diversification & Reach Through: *Home Trial Support*

This service allows Healthcare Professionals to go to the patient, conducting clinical trial visits outside of the site, in their home, school or place of work. With approximately **12% of our visits taking place outside of standard clinic hours (equating to well over 2,000 a year),** this approach increases flexibility for the patient and removes some participation burdens and barriers.

MRN's Home Trial Support Service works with Healthcare Professionals typically within a 60-mile radius of the patient. We have a dedicated network of Healthcare Professionals who are invested in MRN's vision of making trials more inclusive and accessible for all patients.

Our HCPs have been carefully selected and are chosen not only because of their clinical capabilities, but also their ability to relate and empathize with those under their care.

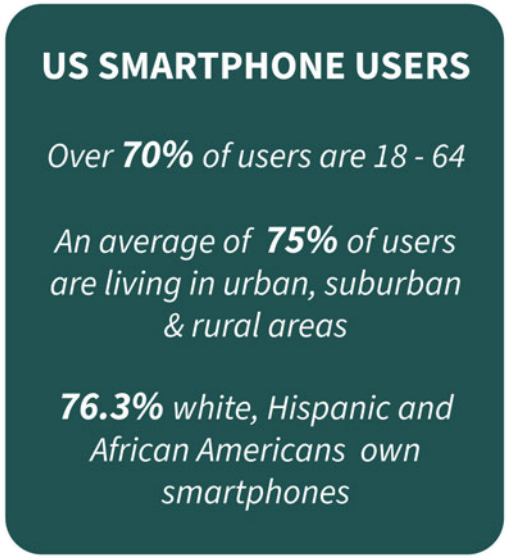
The cultural and religious needs, as well as the medical needs of the patient are considered when selecting our HCPs to ensure every care is taken to ensure patients feel comfortable with essentially a stranger (at first) in their home. This is of paramount importance to MRN and our HCPs as they will be a part of the patient's journey throughout the trial.

This method can work to serve a greater number of patients from a greater number of communities – allowing for increased geographical reach of diverse patient populations while keeping their care local to them.

Diversification & Reach Through: *Technology Connecting Sites, HCPs & Patients*

In today's world, it would be amiss not to consider just how much technology does and can play a role in reaching more patients and more 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 by 2025.[11]

These stats are encouraging – they offer another avenue of reaching those who are not near or unable to travel to sites. That being said, the question has to be asked - who actually has access to a smartphone?



The good news is that disease does not discriminate based on which cellular device you own and the stats back this up - there is clearly significant diversity amongst the smartphone

These statistics show that mobile devices and technology are not to be ignored when it comes to designing patient-centric clinical trials – they should be playing a significant role.

There are multiple ways in which these devices can be leveraged to provide remote access to clinical trials. Tools, such as ePRO or eCOA – digital devices designed for patients to remotely collect their own data and transfer it to site, and eConsent – tools designed to fully inform patients about the trial, allowing them to consent and or reconsent to participation remotely.

The use of technology has a lot of pros to it but, as with all things remotely human operated, it is prone to issues. These can include, but are not limited to:

User Error

Patients may not always save information correctly. There may be a technology failure, or simply a lack of experience with their device / app can inadvertently lead to important information not being captured and submitted. The risk here is that information may not always be retrievable.

Technological Error

Sometimes tech fails us, and even the most competent users are not always able to remotely fix issues. Even with the help of a remote technician, this can lead to patient's getting frustrated as their time and energy get sapped by trying to (sometimes repeatedly) resolve issues. This could lead to the patient dropping out of the trial all together – especially if issues persist.

Data Protection Issues

Data protection is of paramount importance, especially as technology becomes more and more advanced. With patients using personal devices, there is a risk that the data they capture, and report is more vulnerable that when it is done on a secured site / HCP managed device.[19]

Limited Face-to-Face Interactions

We should also consider the human interaction element. Many patients in diverse population groups have a strong mistrust of the healthcare system and clinical trials in general. Face-to-face interactions where the patient can be reassured can be critical to instilling a sense of trust and caring for the patient's needs in order to participate.

Another aspect to consider is the benefit of a second set of eyes – patients don't always recognize symptoms or even certain aches and pains as they may have lived with them for extended periods. An HCP is more likely to pick-up on these as they are looking for them and / or have the training to recognize them.

MRN in-home healthcare professionals are able to take this one step further as they can liaise directly a patient's physician and flag things in the home that need addressing for the patient; **for example, an MRN in-home nurse noted a patient would benefit from hand rails in the home and was able to put that in motion by liaising directly with the patient's primary physician.**

Technology is here to stay but as it develops it can, when used correctly, play a pivotal role in new, evolved clinical trial models.

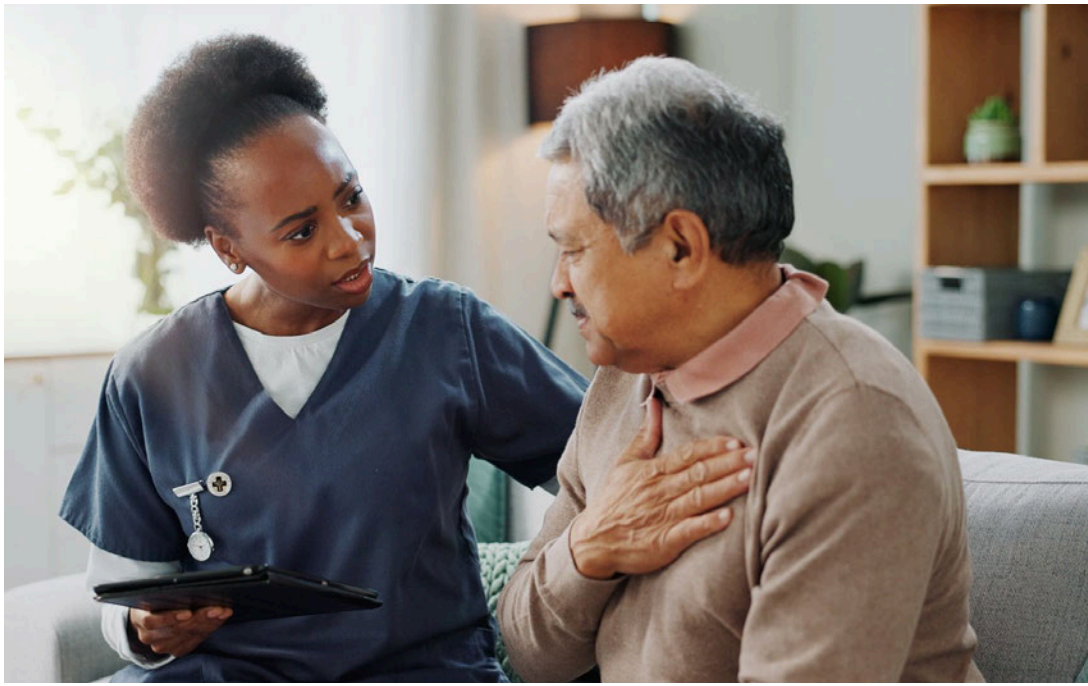
So how do we maximize on the use of technology in clinical trials, while mitigating the risks?

By having the HCP manage the technology that is taken into the patients home.

Not only does it ensure that the device and software being used is both compliant and regulatory approved, but it is also rigorously protected from accidental and malicious data theft / loss.

MRN's technology tools are integrated across our solutions. This makes it possible for used by Sponsor Sites, Home Visit HCPs and MRN Network Sites to seamlessly collaborate and efficiently capture robust and integrated data from any location.

The tools and systems are designed to provide simplified processes for sites and patients all the while **improving patient compliance,** extending the range of assessments that can be completed in the home, **providing a communication platform for physicians and patients**, and allowing additional physician oversite. This creates a unified data collection platform and safely and securely **provides more complete and accurate data.**



An Integrated Approach

Conclusions

An Integrated Approach

Trying to understand what fortifies an ecosystem is in fact, not actually an easy thing to do. Even when looking at nature, there are no apparent hard and fast rules that anyone can agree to. Except for one simple, yet elegant concept of what makes a system resilient - "the ability of a natural system to absorb the effects of change, reorganize itself and adapt to the new context while essentially maintaining its previous structure and functions."[20]

An integrated approach can create a sustainable ecosystem for clinical trials.

Utilizing in-home, at-site and technology solutions, can deliver faster and more efficient trials. The use of a site network will then broaden the reach of these trials – reaching untapped, diverse communities, and increasing trial reach, recruitment and retention.

Adapting to change, and in extension, evolving the approach taken when conducting clinical trials is no easy task**. This is why working with organizations like MRN is critical to building effective and efficient trials.** It is the knowledge and understanding of community-based trial-delivery and the needs of diverse populations that enable MRN to collaborate with sponsors and sites.

Through in-home visits, empowering and enabling more sites and more physicians to participate in clinical trials via our site network, **we deliver flexible trials that enable improved recruitment, enrollment and retention rates. This in turn creates more efficient, more accessible and more diverse clinical trial ecosystems** – creating a win-win system that is sustainable.

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