# How Decentralized & Community-based Solutions Can Drive Change In Women's Healthcare

By Medical Research Network

March is designated as Women's Month - a time to recognize the contributions of women, reflect on the challenges they face, and explore how we can better support their health and advancement.

***However, this article is being published in August***, and this is intentional. Why? Because, when it comes to women's health in clinical research, discussions around gender equity, representation, and access must extend beyond a single month — or a single day — if we aim to drive meaningful, lasting change.[1]

## Women & Healthcare

Across cultures and countries, women, for the most part, have become the family designated caregiver. This is regardless of whether they have children or not – the role of caring for grandparents, parents, nieces and nephews or grandchildren in most circumstances falls to the women of a family, and it has for centuries. This level of responsibility, as well as increased pressure and stress, is a key contributor to poorer long-term healthcare and treatment in women.[1,2]

The role of motherhood has also played a (not too) historic part in female exclusion from clinical trials. The thalidomide medical disaster of 1962 led to all women of childbearing age (regardless of whether they wanted or could have children) effectively being banned from clinical trial participation by the FDA in 1977. The fear was that there was potential for them to fall pregnant during a trial, leading to other medical tragedies. This was only reversed in 1993.

The view on women's health has not much improved since then, with reproductive health (including breast cancer) often being viewed as the unofficial definition of women's healthcare.[3] A quick internet search confirms this, as lists for gynecologists and breast screening sit at the top of the returned results.

This narrow view of what women's health actually is, coupled with the fact that women are more likely to suffer from illness and disability during their lifetime,[4] is a concerning one – especially in a time where there is a greater drive for diversity and representation in clinical trials.

## A More Nuanced Understanding Is Needed

When it comes to women's health, a more holistic view is required – from both the medical and research community and women themselves.

When we speak to women's health, it needs to be understood that we are speaking to how symptoms to diseases may present differently, how treatments & therapies may affect women differently, and yes, how women's metabolic, reproductive and hormonal balances will be affected by new and existing treatment and therapies.

There are also conditions that have previously been associated with men yet have greater prevalence in women. A good example of this is Alzheimer's disease – with a 2013 study finding that the chance of women developing Alzheimer's was double to that of men ( OR = 2.57; 95% CI = 1.60–4.11). A further study conducted in China in 2021 found similar – women were twice as likely to develop Alzheimer's that their male counterparts.[5]

Other conditions that are more prevalent in women but need greater participation in trials and more awareness about how symptoms may present very different include, but are not limited to, HIV/AIDS, Multiple Sclerosis, and the number one silent killer of women – heat attacks.[6,7]

Driving a more nuanced understanding of women's health forward is the first step to creating greater equity in healthcare. It also opens the door to more inclusive conversations between women and their primary physicians about their health and, where appropriate participation in clinical trials.

## Enabling Participation In Clinical Trials

While women represent nearly half of the world's population,[8] only 41% are represented in clinical trials. On the surface that number doesn't seem insurmountable, but when we start to consider ethnicity as well as therapeutic area, the numbers start to widen significantly.[9,10]

A study that reviewed clinical trials between 2016 - 2019 found that the number of women participating in trials was not proportionate to the patient population, with examples in psychiatry (60% patient population vs 42% trial participation) through to oncology (51% patient population vs 41% trial participation).[9]

Further, the intersection of race and gender is not commonly recorded, making it even harder to realize the full picture of both representation and, in-turn, efficacy of treatments and therapies. However, where this data is captured, such as in a 2016 cardiology trial, it showed that just 3.2% of women enrolled in the trial were African American or Black.[10]

While changing the narrative is the first step, as discussed, how do we, as an industry, then facilitate participation moving forward?

## *Bringing Trials Home*

Or to a suitable and convenient location for your patient. Given that for many women additional caring and family management logistics are left to them to manage, making clinical trial participation doable is critical to increase participation. And one of the more obvious ways to make participation doable is to make it one less thing that requires extensive time and intensive logistical planning.

Home Trial Support (HTS) is one of the solutions available to sponsors and CROs to enable more women to participate in clinical trials. This solution is focused on bringing as many trial visits as feasible (something the Principal Investigator will determine and discuss with the patient) directly to the patient, wherever that location may be. This eliminates the need for ongoing travel to and from the trial site and limits the additional caregiving arrangements that may need to be made to facilitate participation.

Immediately, by removing these barriers, clinical trial participation becomes less of a burden and more of an option for many women. Additionally, this encourages continued trial engagement – increasing retention rates.

Time and logistics are the more obvious barriers to trial recruitment and retention for women, but the unspoken barrier is, being listened to. Historically, when women have spoken to their symptoms they have either been dismissed or attributed, incorrectly, to something else (like stress from caregiving).[1,11,12,13]

HTS Healthcare Providers (HCPs) are in a unique position where they not only have the time to listen to and discuss the patient's symptoms and reactions to the treatment they are undergoing, but they are also able to observe the patient's daily life.

This provides keen insight into how the environment the patient is in directly impacts them and their health. The HCPs are then able to report back to the study teams, and more accurate, representative data can be collated – making a significant difference to a treatment or therapy safety and efficacy profile.

## *Easing Access With Community Care*

While HTS provides the most flexible care, it may not always be suitable based on either the trial protocol or the patient's preference. However, this does not mean that Sponsors and CROs should return to traditional trial designs and sites. Instead, they need to look at utilizing solutions that still provide an improved level of flexibility and accessibility. Community-based sites are well-placed to provide this.

When well supported, community-based sites can offer patients access to trials that are closer to their home and/or workplace, participation and continued engagement through to the end of the trial is likely to be much higher. Study staff at these sites are also often more representative of the community they are treating, again, providing better insight into what environmental factors may impact their patients.

Another alternative is the use of satellite trial sites – a marriage between community-based sites and HTS. Well-managed temporary community-clinics or satellite clinics come into communities and effectively operate as a community-based site. They are also, often, able to offer more flexible appointment times to patients than traditional site models can.

Sponsors and CROs looking utilize community-based sites should ideally look to site networks that not only provide the necessary support to their sites but also utilize community clinics. This enables maximum reach for the trial, and the higher probability of recruiting not just women, but a truly diverse population matrix.

# Conclusion

The path to inclusion and the closing of the gaps between men and women in clinical trials are clear.

Firstly, understanding that the barriers to participation are systemic and addressing them requires ongoing commitment from the clinical research and healthcare communities.

Secondly, a proactive approach needs to happen. Clinical trials need to be designed around the population the therapy ultimately aims to treat. If more women than men are affected by a condition, this must be reflected in the trial data. To do this, barriers to participation must be reduced or removed wherever possible.

The conversation around women's health is not and should be a seasonal one. To drive real change it needs to be continuous, inclusive and result in actions being implemented by industry leaders to address disparities. Anything less risks impeding the advancement of equitable care and continued disparities in women's healthcare.

*Tell me how MRN can help my trial drive change through their HTS and Site Network services.*

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# About MRN

MRN accelerates patient recruitment and improves patient engagement and retention through site-centric and patient-centric solutions.

As an innovative market-leader, MRN provides customized solutions to optimize each individual protocol and create more flexible, efficient and accessible clinical trials that deliver accelerated timelines.

Through integrated in-home visit delivery and a vast global network of trained, research ready sites, all empowered by MRN's digital solutions, MRN engages with and empowers diverse communities around the world to participate in and advance medical research.

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