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Prepared by Medable Contact: Lisa Barbadora / lbarbadora@bigvalley.co

**The Other Half: Decentralized Research is The Path to All-Inclusive Medicine**

By Sanskriti Thakur, *Chief Growth Officer*

Medable

More than 50% of the U.S. population is projected to be “other than non-Hispanic white” by 2045.1 If the current clinical research process is not urgently reconsidered, the life sciences industry will continue developing drugs and devices that only work for a select few, leaving out the ‘other half.’

Despite efforts, including those from the U.S. FDA and the Revitalization Act of 1993, which required that clinical trials funded by the National Institutes of Health include women and minority participants, diversity in clinical trials has not substantially improved. At least 83% of research participants are white even as they make up only 67% of the U.S. population but African Americans make up 13.4% of the U.S. population and only 5% of trials. Hispanics represent 18% of the population but less than 1% of trials.2

Participants in clinical trials should reflect the diversity of the population – not just for altruistic reasons. A lack of representation from minority groups in research has resulted in interventions that have not translated well in the real world, squandering efforts, and even proving harmful in different populations. For example, 5-Flurouracil, a commonly used cancer chemotherapeutic drug, often exhibits differences in drug response among different populations.3 A major side effect associated with the drug is the occurrence of hematologic toxicities, including leukopenia and anemia, and often found in higher rates in underrepresented populations. Not surprisingly, 5-Flurouracil’s clinical trials were overrepresented with white participants, missing the opportunity to assess the adverse effects in minority groups.

Generally, the industry has poor outcomes and unexpected safety issues – and this is one of our greatest R&D costs. When data from diverse populations is lacking, additional post-marketing studies are often recommended, proving costly. Yet drugs are still sold, the cycle resumes, and remedies continue to be developed for a sliver of the population without accounting for different demographics, geographies, genomics, and ethnicities. Thus, they fail or cause adverse events. According to the FDA’s Center for Drug Evaluation and Research, approximately two million serious adverse events occur annually in the U.S. and are responsible for around 100,000 deaths per year. They also cost the industry between $30 billion and $130 billion annually.4

We are making drugs for one population. The rest are not even *aware* of potentially life-saving clinical research opportunities. Misinformation, politics, money, distance, fear are all contributors to why medicines remain suboptimal. It must change.

Finally, fortunately, the foundation has been laid to make clinical research more accessible with better outcomes. Decentralized clinical trials, hybrid trials, remote clinical trials, adaptive clinical trials – these boundaryless research models are possible now thanks to technology and a patient base eager to use it.

Here are three reasons why an inclusive, adaptive, decentralized model for research is the future:

1) **Patients demand more.** For the first time, the masses experienced remote treatment during the pandemic, and they will continue to expect it. [In one survey](https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/helping-us-healthcare-stakeholders-understand-the-human-side-of-the-covid-19-crisis), up to 98% of patients reported satisfaction with telemedicine. In another, 72% of physicians reported similar or better experiences with remote engagement compared with in-person visits. Indeed, patient-centric healthcare is possible with technologies built of human-centered design principles.

In a real-life example, patient Jesse Venticinque participated in a clinical trial for a COVID-19 [interventional treatment trial](https://clinicaltrials.gov/ct2/show/NCT04321096) after he tested positive in February.He was initially hesitant. As a husband, father, and co-founder of a startup fitness company, Jesse didn’t have time to devote to regularly visiting a clinic an hour or more away from his home. However, as a hybrid study, it only required four in-person site visits. All other aspects of the study were remote. Jesse had a positive experience, even suggesting the use of additional remote tools. “The study materials, such as the informed consent forms were on paper, but I would have preferred that all to be digital,” Jesse noted.

2)  **The efficiencies are irresistible.** The $2.6B+ cost per product for developing drugs is still growing especially where personalization and cell and gene therapies challenge the system. Decentralization breaks from the traditional model to drive costs down by reducing time to market, improving trial efficiency, and enabling better outcomes for a more diverse population. Leveraging hybrid and remote technologies, scientists can test new therapies at pace in smaller but more representative populations without investing in as much brick-and-mortar infrastructure. For instance, community pharmacies and local urgent care centers can become cost-efficient, convenient site locations for certain therapeutics while telemedicine reduces travel and cost burden for patients as well as sponsors.

3)  **Precision medicine is becoming mainstream.** Targeted therapies accounted for just 5% of new molecular entities approved by the U.S. FDA in 2005 but [accounted](https://health.oliverwyman.com/2020/02/personalized-medicine-is-about-to-go-mainstream-with-big-implica.html) for more than 40% in 2018.5 That’s great news, but it also makes finding the right patients to fill those niche research opportunities difficult. With advanced technologies now available to include smaller cohorts of patients in these trials, there is an incredible opportunity to completely dismantle the current paradigm of clinical research.

Today, [three-fourth of companies](https://www.oracle.com/uk/news/announcement/covid-19-tipping-point-decentralized-clinical-trials-2020-11-18.html) say they are running “some decentralized trials”,6 the U.S. FDA is expected to offer [new guidance](https://www.centerwatch.com/articles/25570-fda-expected-to-issue-draft-guidance-on-decentralized-trials-in-2021) for operating decentralized trials,7 and [100 industry leaders](https://www.globenewswire.com/news-release/2021/04/26/2216839/0/en/Decentralized-Trials-Research-Alliance-DTRA-Reaches-Milestone-of-100-Member-Organizations.html) make up the newly formed Decentralized Trials & Research Alliance (DTRA).8 Additionally, the continued rise of precision medicine and gene therapies means that diversity in clinical trials is now more crucial than ever to obtain a complete picture of a drug’s safety-efficacy profile.

The industry is at a critical inflection point. Do we continue to make drugs that treat just half of the population? Or do we adopt new clinical research models that enable better outcomes? We are now able to move science from product to platform, creating technological access to medicine for everyone. It’s an imperative for health equity. Without it, medicine is not made for everyone.

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**About the Author:**

Sanskriti (“Sans”) Thakur is Medable’s Chief Growth Officer and is focused on market expansion and growth initiatives to advance the company’s vision of human-centered research, enabling remote access to clinical trials regardless of geography, income, and race**.** She most recently served as global life sciences research lead for Accenture, responsible for market-shaping strategy and research in therapeutics, digital health, and business model innovation. During her 18 years in the life sciences industry, Thakur has advised more than 30 companies, launched 10 products, advised digital health venture funds, and managed a leading pharmaceutical portfolio. She has authored 12 publications on various industry topics, and currently serves on the World Economic Forum global futures council for healthcare topics.Sans can be reached at sans.thakur@medable.com.

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