“Trial-In-A-Box” to help more practices take part in clinical trials

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Just 3% of the nation’s physicians and patients take part in clinical trial research that leads to new therapies, according to Food and Drug Administration (FDA) data.

On top of that, large academic health systems conduct most of the trials. That means they reach few medically underserved populations and that nonwhite populations participate at rates less than half of what their representation is in the general population.

But SiteBridge Research Inc.—recently spun out of Health2047, which is the wholly-owned innovation subsidiary of the AMA created to overcome systemic dysfunction in the U.S. health care system—plans to make clinical trials more accessible to community-based physician practices that traditionally haven’t had the resources they need to function as clinical trial sites.

In turn, clinical trials will gain enriched real-world data and real-world evidence from patients who live too far from academic centers to participate in studies and ultimately have clinical trial results that better reflect the nation’s diverse population.

SiteBridge executives say they hope to cut the time it takes for drugmakers to bring new products to market. They also aim to help traditionally harder-to-reach communities whose needs have gone unmet more quickly adopt therapies that benefit their health.

“Our national experiences during the pandemic have highlighted the need to advance health equity and as part of that commitment, we need to continue to find ways to connect more broadly into the community,” said SiteBridge’s co-founder, Manesh R. Patel, MD. He is chief of the division of cardiology and division of clinical pharmacology at Duke University School of Medicine.

Dr. Patel added that expanding clinical trials into areas outside of large academic centers is “the right
thing to do and will help get the most innovative treatments to the patients who need them most.”

Learn what the AMA is doing to promote health equity in the United States.

**How SiteBridge will work**

The company has created what it is calling a “Trial-In-A-Box.”

The platform provides access to:

- Clinical research training.
- Resources and support, starting with the initial feasibility and site start-up and continuing through the full study delivery and close out.
- Flexible, centralized and on-site support to remove administrative burdens so physicians can focus on supporting patients.

SiteBridge is developing a network of physician thought leaders who already work with pharmaceutical companies and can collaborate with the industry to create research study designs and develop strategies that target broader sites and a more diverse patient population.

“As health systems vow to improve health outcomes by tackling social determinants and inequities, it’s critical to ensure clinical trials represent the broadest possible patient set,” said SiteBridge CEO Chris Komelasky, who comes from the pharmaceutical industry. Komelasky was previously an executive at PPD—a global pharmaceutical contract research organization—and at GlaxoSmithKline.

He said that SiteBridge’s platform “facilitates the participation of smaller physician practices in trials so research studies can have more representative patient populations for the intended applications of the drugs being tested and create more realistic risk-benefit profiles for new treatments.”

The platform “puts the focus of research on the trusted relationship between a physician and patient,” Komelasky added.

**Democratizing trials**

The pace of research has accelerated in recent years and the patient pool that studies can include has become more limited as more restrictive inclusion and exclusion criteria have been put in place.

The changes have made it difficult for pharmaceutical companies to find the patients they need
through saturated large academic centers. Yet it’s also been challenging for small and community practices that could expand research to be considered as trial locations. SiteBridge wants to build a national network to change that.

“This involves enabling trials to occur at point-of-care versus traditional large academic institutions,” said Health2047 CEO Lawrence K. Cohen, PhD. “We’re excited by SiteBridge Research’s mission to democratize clinical trials by opening access and removing barriers to different parts