

Bioclinica Debuts New Divisions to Support Patient Engagement

By Lisa Catanese

In a strategy to address the industry-wide challenges of patient engagement in clinical trials, the specialty services provider **Bioclinica** has announced the creation of two separate divisions, a Research Network and Patient Recruitment-Retention, under the company's Global Clinical Research business segment.

Together the two divisions will create an integrated offering focused on patient engagement, said John Hubbard, Ph.D., president and CEO of Bioclinica, which publicly unveiled the concept at this week's DIA Annual Meeting in Philadelphia. "Our view is that by combining these two modalities, we could accelerate and enhance the ability to enroll and retain patients," he explained. "We've combined best-in-class approaches in recruitment and using our centers as a vehicle to bring patients in."

Experts point to problems with awareness, understanding and trust among potential trial participants as well as providers that persists today. They also cite the disconnect between a patient's interest in participating in a trial and actually taking the next step to enroll. Other challenges include difficulty in enrolling more diverse populations, recruiting specific patient types for targeted studies, and the costly fact that up to 10 percent of enrollees are lost to follow-up.

"Patient recruitment is challenged by the ever-growing complexity of protocol inclusion, exclusion and regulatory constraints," said Jennifer Byrne, chief executive officer of **PMG Research, Inc.**, an integrated network of clinical research facilities. "But even more

than that, there is a general lack of knowledge about clinical trials at the provider and the healthcare system level."

The barriers are daunting, but efforts to open the curtains on clinical trials are stepping up. For example, in recent advertisements, both **Bristol-Myers Squibb** and **Pfizer** have included messages of thanks to patients and providers who have participated in trials, as a way to raise awareness. "That's a fabulous example of the industry doing something very positive," said Christine Pierre, president of the **Society for Clinical Research Sites**.

Today's technology, in particular social media, is presenting new opportunities to identify, educate and engage patients. "We are using patient recruitment strategies that have become much more digital in nature," Hubbard said, citing patient communities, websites, chat rooms and electronic medical records as options to identify appropriate subjects.

Better recruitment strategies are even more critical in light of the industry's move toward more trials involving precision medicine, in which a narrower group of specific patients with certain disease characteristics will be needed.

Improving the patient experience is one of the keys, said Elizabeth Thiele, president of Global Clinical Research at Bioclinica. "The real topic today is patient centricity and engagement so we can design better clinical trials," she explained. "In many instances when protocols are developed, sometimes they feel awkward and are hard to operationalize because there are so many things we want to study scientifically."

The sites themselves are untapped resources in the recruitment struggle, Pierre pointed out. "The sites are an extension of the patient and have a unique perspective," she said. "The site and the patient are hand in glove, and those two stakeholders have been vastly unrepresented in this industry. When I look into my crystal ball, I see different faces sitting around the table at strategic points, talking about their area of expertise so that we can all ensure we are getting medicines to patients faster. Ultimately, that's going to help immensely in moving the needle."

Changing the impression that clinical trial participation means being part of an "experiment" can also be a viable recruitment strategy, Byrne noted. "At PMG, we've been passionate about driving clinical research as an option within the continuum of care for a patient," she said. "If the value proposition for research participants is being part of the greater good and advancing science, what if we say that through this program you'll learn more about your condition and have more touchpoints with highly specialized professionals, and you will come out of this a more informed consumer and active participant in your health and wellbeing."

As with many aspects of the research arena, the wheels turn slowly—but they do seem to be turning, observers say. "I think there are a number of organizations that are investing heavily in understanding the patient journey from the ground level instead of from the ivory tower," Byrne said. "There is a lot of exciting and transformative work for us to be doing, rather than looking back over our shoulder in terms of the way it was done ten years ago." 