Rhonda Henry
Vice President, Site Collaborations and Patient Centricity
PPD

Rhonda Henry has more than 27 years of clinical research experience, all of which have been with PPD. As vice president of site networks and patient centricity for the global contract research organization, Henry develops PPD's site network strategies and patient-centric trial models to improve the company's sites and patients capabilities and expand its service offerings. A graduate of the University of North Carolina Wilmington, Henry began her career as a registered nurse before entering the industry as a clinical research associate. More recently, she held leadership positions in project, account and alliance management.

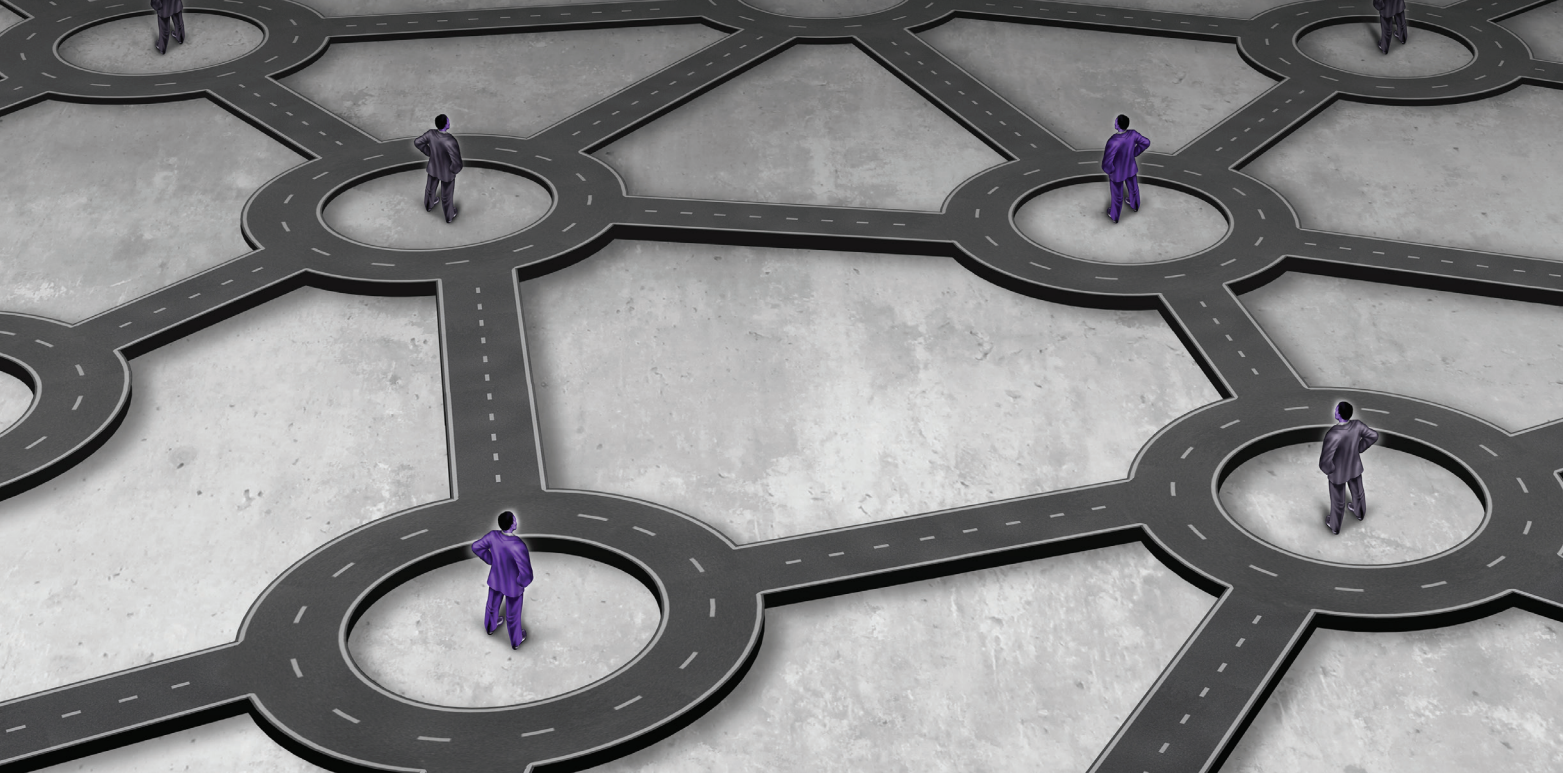
What are some of the current critical issues facing the industry in regards to clinical trial patient recruitment?

Patient recruitment in clinical trials is a major industry challenge. According to clinicaltrials.gov, the number of registered clinical trials has more than quadrupled over the past 10 years (from approximately 66,000 to 281,000) significantly increasing the need for clinical trial participants. On the other hand, approximately 48 percent of sites do not meet their enrollment targets and 80 percent of studies are delayed due to patient recruitment challenges.

Numerous publications point to the same common barriers to patient recruitment as being:

- Lack of patient awareness about clinical trials as a possible treatment option – Patients rely on their health care professionals to guide them to the best treatment options. Consequently, if the patient's physician does not conduct clinical trials, the patient is unlikely to be invited to participate in one. As an industry, we recruit primarily research-experienced sites supported by past performance data to conduct our trials. Inherently this means we saturate the same sites with clinical trials that compete from the same patient pool while there are a significant number of sites and patients unaware these trials exist as options. One way to address this paradigm is to use patient data sources, like Acurian, to identify interested and eligible patients and refer them to participating study centers. Some site networks, like Synexus, have optimized their processes to support such patient-centered engagement. Another approach we take at PPD is to leverage a variety of internal and external patient data sources to identify sites with the appropriate patient population and then identify and support those sites in becoming productive, high-quality research sites.

- Limited or no local access to a clinical trial – According to ASCAN.org, on average, 56 percent of cancer patients in the U.S. will not have access to a clinical trial local to them. Through Optimal Oncology Research Network, PPD offers a network of oncology research-experienced community practices that are committed to bringing more trials as treatment options to patients where they live. By leveraging this model where the full network of near 300 sites perform pre-screening to identify patients first, followed by rapid "just-in-time" site activation for those sites with identified patients, the industry is able to offer trials to more sites and their patients while avoiding the expense of setting up sites only to wait for patients.



- Protocol complexity – According to CISCRP, the number of protocol endpoints and eligibility criteria has almost doubled and the number of required procedures has increased by 50 percent over the last 10 years, both of which adversely impact patient participation in clinical trials. Within PPD, we leverage our patient research scientists, supported by significant drug development expertise, to bring patient perspectives to our sponsors to optimize their protocol and trial, as well as to avoid costly protocol amendments that often result from overly complex protocols and impossible-to-enroll studies.

Can you tell us about some recent technological innovations that are helping pharmaceutical companies meet their clinical trial participant requirements/goals?

Recent technological innovations, many born out of patient centricity efforts, are beginning to help pharmaceutical companies meet their clinical trial participant goals. There are numerous patient data technology providers that enable the industry to conduct data-driven feasibility as opposed to the surveys providing site-reported patient numbers that had been used in the past. The information gained from comparing protocol inclusion and exclusion criteria against real-world evidence can be invaluable in designing a better protocol. Previously, necessary adjustments to eligibility criteria were only identified after the protocol was final and the study experienced enrollment challenges. Technology advances have also enabled the industry to engage patients more efficiently and effectively in the clinical trial process than ever before. With the advent of disease-specific communities and crowdsourcing technologies, patients can provide direct input into the protocol design, which identify and hopefully remove barriers to patient participation. Additional technologies, like mobile patient apps and patient concierge services PPD offers jointly with Acurian, are focused on making clinical trial participation more convenient for patients and their caregivers, which benefits pharmaceutical companies as well.

When a pharmaceutical company is choosing a company to assist them with their clinical trial participant recruitment efforts, what questions should they ask? What qualities and expertise should a provider have to ensure that their clinical trial participant goals are met?

When a pharmaceutical company is choosing a partner to assist with its clinical trial recruitment efforts, it is important to not only understand the company's global reach, therapeutic expertise and track record for operational delivery on patient recruitment, but also to understand what data sources the company has access to. Not all data sources are created equal and, by the same token, no one data source can provide all the answers or patients. It is important to ascertain what type of data is available, how current the data is and whether or not the data ultimately can be identified by the site. Everyone has access to patient data through one source or another. The true value of patient data only can be realized when coupled with site engagement and a detailed site and patient access strategy.

What future clinical trial recruitment innovations do you foresee? How will they help pharma companies test and bring products to market?

Many future clinical trial recruitment innovations will be directed toward patients. Patient centricity will result in the prioritization of patient convenience and experience. Patients should have their pick of clinical trials, in addition to having more options to be treated "virtually" as opposed to traveling to their health care provider's office to be seen in person. Clinical trials themselves will become more "virtual" in nature, resulting in less dependency on actual brick-and-mortar physician offices. Pharma will have greater access to patients globally, but will be more dependent on technology to connect all the dots.