As technology, people, and data become more closely intertwined in the age of the Internet of Things, the pharma industry is finding its tried and true clinical trial model to be increasingly challenged. With the rise of social media, patients are becoming more invested in making their voices heard in the clinical space, says Susan Romberg, VP of global clinical development, NA, Chiltern. Indeed, Romberg says this movement toward patient-centric trials and drug development has been primarily spearheaded by the patients themselves because of the greater number of resources available to them via the Internet.

“More than ever before, patients and their caregivers are well informed about their disease and can more easily access information and treatment options than they could just a few years ago,” Romberg says. “They are more engaged with their healthcare providers, and thanks to the Internet and social media platforms, they are communicating and engaging with other patients who are seeking a community to discuss their disease experiences and the treatments available.”

The pharma industry is no stranger to these new developments, and it has certainly identified the benefits that can come from involving the patients in the clinical trial development process: better written protocols and higher recruitment and retention rates. However, even more importantly, updating protocols to become more patient centric would give the industry a chance to get an inside look into what exactly living with a specific illness is like and alter drug development accordingly.

Romberg says, “This firsthand knowledge of what it is like to progress through study visits and procedures while managing an illness, jobs, and families is not something that can come from within the industry. Patient feedback can be used to develop studies that make patient participation as easy as possible while providing the data we need to take the next step for further development.”

TAKING ADVANTAGE OF THE INTERNET OF THINGS

While social media platforms Facebook, Twitter, and Instagram are hardly new, they remain largely unchartered land for the pharma industry. Much of this hesitance has to do with the lack of official FDA guidance. However, the lack of guidance is not keeping patients and patient advocacy groups from sharing valuable information that pharma can — and should — be mining to move forward. When it comes to patients, Romberg says even privacy laws are not holding them back from remaining connected with each other, which creates the perfect opportunity for pharma to gain more insights for trial development.

“Despite prominent HIPAA laws surrounding patient privacy, patients are freely sharing their personal health information on a variety of websites — for instance, PatientsLikeMe, Michael J. Fox Foundation, and ALS Association, among others — so that their combined data (i.e. patients’ onset and progression of a disease, frequency
of AEs, and alternative treatment options) — can be used to expedite treatments and cures," says Romberg.

She emphasizes the need to integrate a social media component into development teams and project plans, which would in turn enable teams to integrate patients' passion into clinical trial development. To do so, she suggests several members of the development team join forces with the advocacy groups working with the targeted patient population. There are a number of forums on Facebook, for example, where teams can turn to gain access to information both about the disease and its patient population. The use of #hashtags have also played a key role in organizing the world into industries, groups, and movements, and pharma should remain aware of these tools, especially considering the success of the recent ALS Ice Bucket Challenge.

Besides integrating a social media component into development teams and project plans, Romberg also says the industry needs to pay close attention to emerging wearable devices and Bluetooth technologies. She highlights smart-watches, smart phones, fitness trackers, and contact lenses that can track patient's biometric data, while also offering information via push notifications and text messages. Blue-tooth technology in particular holds a lot of promise for patients affected by illnesses, such as Alzheimer's disease or schizophrenia, where dosing schedule adherence can be an issue. While there is still hesitance in the industry about the accuracy of the data made available through these technologies, Romberg envisions a future where these devices and apps will enable patients to remain involved in a trial, regardless of where their lives take them.

Similarly, she homes in on the role clinics, urgent care facilities, and pharmacy chains will play in making the clinical space more patient-centric. Mini clinics and urgent care facilities are currently resources for patients seeking treatment for common illnesses or routine treatments, such as flu shots. However, because many of these facilities are members of a pharmacy chain or are owned by a larger healthcare organization, patient data can be shared more easily across their network. In this case, location would no longer be an issue for patients. Romberg expects that, “Soon, a snowbird from New England participating in a trial will be able visit one of these mini clinics for their trial visit while spending the winter in a warm southern state — It’s coming!”

**WHAT CAN PHARMA DO?**

So how can pharma begin to make patients key players in the drug development process? Getting patients integrated into the process early is key. In the beginning, even offering patients the opportunity to review a draft protocol and procedural schedule can give the patient and the development team better insight into how appropriate and manageable the trial will be for the patient and their illness.

“Begin by asking patients when and how they want to be involved. Something as simple as a discussion around how participating in the clinical trial process would impact the patient could prove insightful for the development team. It’s important to remember that not all patient populations are educated on the drug development process, so partnering with advocacy groups and providing education on the drug approval process should be a first step.”

Involving the patient in the trial process can help pharma realize improved protocol designs and targeted site selection, among other benefits. However, the success of this movement is also dependent on a shift in perspective within the industry. According to Romberg, “The industry is too comfortable with how we have been conducting and implementing trials over the years. True change requires real effort.”

This change in clinical development procedure needs to be spearheaded equally throughout an entire organization — regardless of position or rank within a company. A successful transition from sponsor-centric to patient-centric trials ultimately requires forward-thinking leaders who are willing to listen to patients discuss their disease experiences and take this knowledge back to clinical development teams.

In doing so, Romberg argues this will enable the industry to experience firsthand what patients’ go through in the course of their illness, as it is easy to forget the difficulties patients may have managing treatment regimens and side effects while also carrying out their daily tasks. “Frequently, we ask patients to jump through some pretty big hoops,” Romberg concludes. “How can we not listen to what they have to share with us to make their experiences with a clinical trial more pleasant and beneficial for all?”