

In-Office Research Partnership Calls on Physician Investigators

Elligo Health Research and Allscripts are partnering to create Elligo Goes Direct, offering physicians the opportunity to participate in clinical research trials in their own offices and providing patients with convenient access to clinical trials.

Elligo Health Research provides clinical research infrastructure to healthcare clinics, in the form of people, services and technologies, to increase access to patients for clinical trials, while Allscripts maintains an electronic health record (EHR) system and other healthcare intelligence technologies to identify clinics and patients. Allscripts currently connects around 45,000 practices and 180,000 physicians with electronic healthcare resources. They also provide a patient engagement platform, which serves 7.2 million patients. Elligo is inviting sponsors and CROs to participate, offering access to patients and a more diverse, realistic population base.

Chad Moore, president of Elligo, described the reasons behind the formation of this partnership: "The companies share a common vision of providing innovative solutions to optimize clinical trials. This includes improving the speed and efficiency of trials and providing physicians and their patients easy access to new, developing therapies, while enabling revenue generating opportunities for physicians... The Elligo-Allscripts partnership allows CROs, pharmaceutical, biotech and medical device companies access to the 97% of patients in healthcare settings that do not currently have access to clinical trials."

Clinician users of the Allscripts EHR platforms will have access to the eParticipateSM service, facilitating participation in available trials after the EHR helps identify potential study subjects. Elligo will provide CRO infrastructure to the individual sites, including personnel and technology when needed, and an on-site manager for study activities. In order to participate, offices must be deemed "research-capable," a term that Moore describes as encompassing "training, processes and technology." Currently available studies involve the fields of gastroenterology, neurology, oncology, pain, pulmonology, urology and women's health.

Research and direct patient care have traditionally been separate fields, with often less than ideal communication regarding shared patients. However, in recent years the idea of integrating research into patient care has received more attention. Patients like having access to cutting-edge treatments, and integrating the two fields can improve efficiency in both. In addition, the importance of real-world data is increasingly recognized in the clinical trial community. Bringing clinical research closer to the actual world inhabited by patients may mean that trials start gathering data and evaluating outcomes that are more meaningful to patients. The entire experience could become more integrated, with real-world clinical care practitioners identifying gaps in research and development.

A 2015 international survey conducted by the Center for Information & Study on Clinical Research Participation (CISCRP) found that 80% of patients are willing to participate in research studies, but the location of the research center plays a major role when these patients decide whether to actually participate, particularly for survey respondents from North America. While 83% of patients reported that their doctor's recommendation strongly influences their decision to participate, only 18% of study participants reported first learning of their study through their physician's office. Presumably, if physicians are more directly involved in research, they will have greater knowledge of available trials that may benefit their patients.

Jeff James, CEO of Wilmington Health, described the potential benefits of this approach: "Anything that can increase the awareness of clinical trials as a care option has the potential to be very positive for both the patient populations served and for the development process of new therapeutics. In this particular case, execution will determine if this model is sustainable. As long as the quality of the study can be maintained and the burden of conducting the studies is not prohibitive, then this has the opportunity to increase the participation of both patients and providers. It could help reduce the cost and time required to bringing a trial to completion."

However, James added, "It is unclear whether this partnership will help adjust inclusion/exclusion criteria. It is feasible that it can, based on the patient data contained in the Allscripts database."

Conducting selected trials in the familiar environment of a patient's regular office, rather than sending patients off to a research center, has the potential to broaden the pool of patients available to participate in trials and should make it much easier for patients to participate, once selected. The studies will still be conducted by CROs, but the researchers will now allow these remote sites to collect their data. This should expedite the development process for medications, devices and other therapies. In addition, sponsors benefit from data that represents a more real-world sample of study patients. Patients' usual clinicians would be able to identify the most appropriate subjects for a given study, avoiding a common pitfall of direct marketing to patients. Physicians and nurses will be more actively engaged in the research process.

James noted, "Traditionally, training is required to become an investigator. This new model must contemplate that aspect."

Receiving trial care under the same roof as usual care facilitates communication between the two areas and allows patients to obtain the benefits of study participation that they might otherwise not be able to receive (for example, if transportation to a study site is an issue). In addition, patients will be receiving care from a clinician that they already know and trust. At the same time, physicians who might otherwise not have gotten the chance to participate in clinical research can do so, improving their knowledge of developing therapies in their realm of expertise and decreasing their knowledge gap regarding available studies that may be appropriate for their patient population.

This partnership reflects a growing movement toward incorporating clinical care into research. By removing barriers to study participation and retention, patients and researchers benefit.

Moore said, "Elligo can improve the diversity in clinical research. Our Goes Direct approach empowers all qualifying patients with the ability to participate in research. Some healthcare providers in underserved communities don't have relationships, connections or partnerships with sponsors or academic medical centers to enable their patients' participation in research. The Elligo-Allscripts partnership is able to stratify patient populations to assist sponsors in designing, powering and conducting clinical research."

The key component of this partnership is likening EHRs with clinical research. Previous attempts to integrate research and patient care have been critiqued for not incorporating EHRs. This new partnership addresses that criticism by making the EHR an integral part of study recruitment. In this aspect, the Elligo Goes Direct program joins other early adopters of EHR technology to identify study candidates, including the Mayo Clinic, the Holston Medical Group in Tennessee, and the Research Institute of Deaconess Clinic in Indiana.

— Julie Quinn

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