Insider Insights:

AMC Health, Clinical Trials division

CWWeekly's semi-monthly company profile feature, Insider Insights, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with Michael J. O'Brien, president of the Clinical Trials division of AMC Health.

Q

AMC Health brands itself a provider of telehealth and end-to-end support services. Given the company entered the clinical trials arena just 10 months ago, how do you envision telehealth for this new division, and what challenges do you see as the newcomer to the industry?

A

A simple way to think of telehealth is that it provides connectivity to patients. I think in this regard, as we advance toward a more patient-centric approach in the way clinical trials are conducted, telehealth can be an important bridge between sites and patients, allowing for the remote collection of clinical trial data.

AMC Health started more than a decade ago, focusing its attention in the area of providing telehealth solutions to managed care, and has been providing that technology to more than 70,000 patients and collecting more than 100,000 data points.

Our vision of telehealth in the clinical trials division is to create a stable, secure application in which a patient and a researcher in separate locations can be connected and where trial data is accurately collected, transmitted and stored. In clinical trials, telehealth can offer benefits to sponsors, sites and patients alike. For the trial sponsor, it offers a remote clinical trial visit, an opportunity to collect data during the normal course of a patient’s day-to-day living. For the clinical research site, telehealth can broaden the reach to identify and interact with patients remotely. For the patient, telehealth can provide another level of comfort, convenience and engagement while participating in the trial.

Sometimes it takes a newcomer to produce significant change in an industry that has been slow in adopting new technologies. We’ve all learned a lot about how technology can transform our industry. Over the last decade we have seen newcomers introduce new technologies such as EDC and ePRO in our industry, and they have gained broad acceptance. We are optimistic that this history of eClinical implementation will allow a more accelerated adoption curve for telehealth. So the focus of our attention is to provide a 21CFR11 compliant application for Remote Clinical Trials Visits, a reliable and efficient way to connect sites with patients while improving the trial experience.

Q

As the industry pushes for patient-centric trials, what was AMC’s focus in developing its platform for Android tablets and smart phones to remotely collect clinical trial data, given the existing rival networks?

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The basis for our positioning Android as our initial operating system to launch the platform around was due to its openness and its flexibility, which allows us a much easier way to roll out new features. We know today that Android dominates the market for new devices deployed, and the economics of Android smart phones makes it more attractive from a financial perspective. So we felt it was the right initial move.

But as part of our future development plans, we intend to broaden the mobile platform to work with other user-owned devices, including Apple’s iOS and Microsoft’s Windows.
operating systems. The important point here is that the mobile platform should reflect the devices patients are comfortable with.

The researcher will access the application through a common internet connection.

**Q** Several companies have become leaders in electronic Patient Reported Outcomes (ePRO), developing various ways to capture patient data and communicate with sites. How does your system go the next step to provide more meaningful interventions with patients via video and voice?

**A** We are providing the opportunity for a remote clinical trial visit that captures all types of information required for trials. There is something really transformative about the way video contributes to the experience by providing a full patient narrative to the interaction with an investigator or coordinator. It shifts the level of interaction from a simple transmission of data points to a richer contextual interaction to evaluate the health status of a patient in a trial.

Combining these technologies enables the concept of a virtual visit, which can be used in a variety of different ways by the clinical researcher. The initial version of our platform incorporates a smart phone or tablet device that serves a variety of functions to collect and transmit data collected from mobile health devices, transmit patient-reported subjective data and measure medication adherence. It also is combined with a bi-directional video capability that enables sites to engage, observe and monitor a patient remotely.

So depending on the individual needs of the study and the features of telehealth that are implemented, we believe this can improve study efficiency, patient safety, medication adherence, protocol adherence and, ultimately, create a more engaged patient in a clinical trial.

The concept of ‘next step’ is dependent on what goals our sponsors are trying to obtain. We are building an application that allows key aspects of a clinical site visit to be replicated at a patient’s home. Some sponsors want only remote collection of biometric data from mobile health sensors. Some want to combine that information stream with patient self-reported data, and others want to collect all of that data plus engage in a video visit.

**Q** What are the biggest communication challenges involving patients in clinical trials still not being addressed, and do you see other parts of your company helping you address them?

**A** In terms of the communications challenges, what we are trying to do in building this platform is to create the environment for communication to flow in a way that is most effective for the patient and the site. There are a variety of different technologies that will help us achieve that, including the use of smartphones and tablets. But providing mobility to the equation and easy-to-use applications can allow for a more engaged patient, one who is more connected to a trial.

We have learned, over many years, the way that communications challenges can be overcome and how patients are trained to use it. Some want only remote collection of biometric data from mobile health sensors. Some want to combine that information stream with patient self-reported data, and others want to collect all of that data plus engage in a video visit. Sponsor needs, availability of devices, requirements of the protocol and regulation each play a factor in deciding the next steps in any of our engagements. That is why we like to be involved as early as possible and engage all parties with a stake in the study, including the sponsor’s team, site personnel, IRBs, etc.

**Q** Given your previous experience running a small CRO, what is your outlook for adding technology to solve comparable clinical trial issues in Europe and other parts of the world?

**A** We have seen how technology has the power to bring the world much closer and the promise of Remote Clinical Trial Visits should not be viewed differently. Telehealth can bring an additional level of insight and efficiency to global clinical trials and it can collapse the time data can be analyzed from weeks to seconds, as a measurement being taken. It also can reveal a nuance to trending information where there are large amounts of data that can be collected.

Clearly we have seen the potential it can provide in global studies in which each regional territory will have particular regulatory issues to be addressed. But through our efforts to develop a 21CFR11 application and secure our Safe Harbor Certification, we do understand the importance of data being secure, collected and stored. We see continued advancements in sensory technology and telecommunications that make us feel very confident a global telehealth approach to serve global clinical trials is a very achievable strategy, one that we are very committed to.