JCS Interviews Tim Davis of Exco InTouch on the Use of Mobile Technology in Clinical Trials

The growth of mobile technology is now recognised by the pharmaceutical industry as an opportunity to change the way we interact with patients during clinical trials. We sat down with Tim Davis, CEO and co-founder of Exco InTouch to find out why he set out on this path almost ten years ago, and how he believes taking a mobile approach can enhance clinical research for patients and sponsors alike.

You are a pioneer in the use of mobile in clinical trials. What gave you the inspiration to improve patient experience and bring the technology into the clinical research arena?

Back in 2004, I had been working in the clinical trial technology field for some time, and it was clear that the patient experience left quite a lot to be desired. Even back then, mobile technology was quite well adopted, and my co-founder and I realised this would be a fantastic way to reach patients. We found that using the patient's mobile to provide motivation and support through the trials was incredibly effective, but quickly realised that mobiles were also an ideal means to collect data as well, and we ran the first ePRO study with a mobile phone back in 2005. Now, almost ten years later, you can see that mobile phones are well-established and part of everyday life for pretty much everyone in the world. The tremendous developments in technology have given us the opportunity to improve the patient's experience, not just in clinical trials, but also in the field of general healthcare.

The use of mobile technology in clinical research seems to be the topic of much conversation at the moment. Why do you think that is?

I think there are two driving forces, actually; firstly, mobiles are an everyday part of everybody's life; regardless of who they are, what they do, or where in the world they live, chances are they use a mobile phone to manage part of their life - whether that's just talking to their kids, checking bus timetables, or something more involved like mobile banking. So, therefore, when participating in a clinical trial, which obviously takes up a lot of time and has a lot of obligations, this kind of service makes a lot of sense. In addition, the cost of bringing new drugs to market is phenomenal - according to Forbes, when you take into account all the failures along the way, the average cost of bringing a new product to market is now almost $6bn. In clinical trials it's difficult to find patients, it's difficult to retain them, and therefore this kind of service that maintains the relationship with the patient when they're not in front of their doctor can only be of benefit.

Interesting. So how does the use of mobile technology benefit clinical trials?

Within clinical trials the use of mobile is really around maintaining the relationship, maintaining the contact, and ensuring patients feel valued, because at the end of the day they are doing this for the greater good - for people who have similar diseases and similar conditions. It is built around integrating remote monitoring and data collection into the patient's everyday life, and of course having the ability to correlate subjective personal analysis from a patient on how they feel they are doing with objective data from a medical device that is connected to their mobile phone. This gives enormous value to the data construct for that particular clinical trial and, because it is mobile, the data is available, providing the better, quicker, and more accurate model that we've been striving for in clinical research for decades.

Taking ePRO (electronic patient-reported outcomes) as an example, the traditional model has been to provide patients with a fixed device to capture their data. This not only presents issues with lack of familiarity with the user-interface, but having a separate device also means patients have to remember to get them out of the drawer and complete their assessments. Now that people have personal access to mobile technology, it makes sense to utilise that to communicate with them and collect their data, so there is a move towards delivering this technology on the patient's own device – termed "bring your own device (BYOD)."

But, of course, this is not just about a single technology, it's not just about mobile, it could be on tablets, it could be internet TV and a whole range of other devices that connect to these. Medical devices are obviously key, but we'll see more

and more other kinds of devices being included in the future, I think; for example, consumer products such as wearable devices have already been included to supplement more traditional assessments and approaches.

Will clinical trials adopt this 'bring your own device' (BYOD) approach?

BYOD is already being used in clinical trials; we actually first used BYOD to capture data from patients back in 2008. Initially this approach was in late phase trials and vaccination studies, where large dispersed patient populations presented particular challenges for data capture. However, as the concept has been proven, we are now seeing BYOD being used both pre- and post-approval. That not only means more clinical trials can gain the advantages of electronic data capture, it also means that, for all of those studies, it's reducing the costs for sponsors. When patients use their own device it means less hardware to provision, less of a burden for the sites, and it reduces the logistical challenges which, in the past, seriously plagued traditional ePRO provision.

Are there important considerations when implementing BYOD?

The key lies in understanding how to implement a BYOD approach as well as having the underlying systems in place to deploy that effectively and securely. A BYOD approach should be inclusive, not exclusive, in order to reach the maximum patient population. We have developed a device-independent platform that enables us to identify the device in use and optimise configuration accordingly. As well as developing this platform to comply with data protection regulations (Safe Harbor, HIPAA, EU data protection), we have built in the capability to block devices which do not meet display specifications set for each study. This means that through running equivalence studies and setting display specifications, we are now able to include validated instruments in BYOD studies.

How do regulators view this approach?

I've always believed that regulators are open to the use of mobile to collect outcomes data during clinical trials, as long as systems are in place to ensure traceability, just as you would do for any other form of data capture. It was great to hear this confirmed publicly by the FDA recently, when they took part in a panel discussion at the MCT-Congress, an event organised to discuss the use of mobile in clinical trials.

The FDA actively promotes electronic data capture through eSource, PRO, and 21CFR Part11 guidance. The three FDA representatives clarified that they view mobile devices as wireless computers; therefore as long as data can be shown to be accurate and attributable, in the same way as data collected through a traditional computer, there are "no barriers to adoption". The panellists also discussed the use of mobile technology to deliver validated instruments, again supporting the approach to maintain a consistent form factor and design layout. As an industry, we are typically very risk-averse when it comes to regulatory approval, so it was excellent to hear the myths that have arisen around mobile data capture being dispelled so clearly by the FDA. For me, their comment that we are "at the threshold of a revolution in clinical studies" sums it up wonderfully!

So what's next for mobile technology in clinical trials?

One of the most exciting areas is real-world health programs; what we term 'mHealth'. Pharma companies are seeking to expand their role from that of simply drug manufacturer to provide support for patients long term, commonly known as 'Beyond the Pill'. We're building some truly unique platforms for these customers, bringing together all the elements of health support – data collection, alerts, rewards, content etc – into an intelligent system that can analyse and display information in personalised portals. By this I mean personalised for the stakeholder in question, but also we're able to adapt these portals for individual users, not simply according to their personal preferences; we are actually able to adapt the information according to their responses and the status of their condition. So, for example, we can flag to a healthcare professional that a patient has recorded concerning results and may be close to hospitalisation, and at the same time provide additional support to the patient, targeted advice, and more frequent data collection to help them get their condition under control. On the other hand, a patient showing their condition is under control would see very different information: perhaps how lifestyle changes could further help improve their health, or flagging how close they are to achieving a personal goal.

As a result, we are able to feed innovations from these mHealth programs back into clinical trials. We are certainly seeing clients beginning to take elements from these commercial programs back into their trials in the same therapeutic area, so in the future you could reasonably expect these products to be launched with the support of an mHealth program, and ultimately becoming a continuum of technology following the patient through clinical research into a broad healthcare setting.

Tim Davis is CEO and co-founder of Exco InTouch, the leading provider of mobile and digital patient engagement solutions to support the Clinical, Late Phase and mHealth industry. Having worked in the clinical research technology industry for over 17 years, Tim is passionate about leveraging everyday technology to simplify the process of clinical data capture, both for the pharmaceutical industry and for the patients themselves. As a subject matter expert in the clinical technology arena Tim was recently recognized as one of the PharmaVOICE 100 for his vision in utilizing mobile technology to engage patients throughout the clinical trial and healthcare process.
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