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Proprietary Intelligence

CROs consider bringing telemedicine from the general health setting into the clinical trial space, though hurdles lay ahead - experts

Benefits such as reduced costs and improved recruitment, retention for trials

Medidata, Clinipace and Icon all interested in remote monitoring tech

Varying state laws over clinical trial products present uptake barriers

CROs could look to bring telemedicine capabilities across from the real-world setting into clinical trials as a way to cut costs and boost patient recruitment and retention, experts said. However, they warned that drawbacks to applying telemedicine in a clinical trial setting includes technological issues and a lack of FDA regulation.

In the real-world setting, telemedicine is remote electronic communication between healthcare providers and patients, for instance via a video call or wearable device, Richard Kimball, CEO of healthcare technology company HEXL, explained. US insurers are increasingly reimbursing doctors for telemedicine visits via video call, a feature increasingly popular with patients, experts told this news service in a 4 September article.

Potential trial applications

However, with clinical trials getting bigger and pricier, Kimball agreed with Mark Shapiro, vice president of clinical development at US CRO Clinipace, and a second CRO executive that using these virtual telemedicine visits in clinical studies could cut costs and time associated with trial patients having to visit sites and medical transport.

Telemedicine visits could be particularly utilised for fragile patient studies for whom office visits are difficult, or for rare diseases appointments where specialists are often hundreds of miles away, Shapiro, Michelle Marlborough, VP of product strategy for cloud-based clinical service provider Medidata Solutions (NASDAQ:MDSO), and the second CRO executive agreed.

Telemedicine visits could increase trial retention since patients do not have burdensome site visits, Marlborough and Simon Schurr, president of US health informatics company Collaborative Medical Technology Corporation (CMTC), said.

Shapiro, the second CRO executive and Marlborough said their companies are interested in integrating telemedicine into clinical trials. Medidata has worked with GlaxoSmithKline (LON: GSK) on a method development project for mobile health (mHealth) tools in clinical trials and has run its own in-house behavioural study, Marlborough said. It is keen to expand mHealth offerings and partner with different providers to do so, Marlborough added.

Other features linked to telemedicine, such as remote monitoring devices -- for instance glucose monitors and heart rate devices -- could also provide better real-time tracking of patients, collecting data on a constant basis rather than just during site visits, said Kimball and Marlborough. A combination of video calling visual assessment and remote measurement through devices would make telemedicine in trials possible.

Sponsors would be attracted to these capabilities, Kimball added.

Shapiro noted Clinipace and other CROs are very interested in wearable technologies which could track such real-time data from patients when they are not in the doctor's office. Medidata partnered with Vital Connect to use its HealthPatch biosensor to monitor vital signals, for instance, Marlborough noted. Icon (NASDAQ: ICON) is another example; in a 27 November 2014 article a company source told this news service of plans for the CRO to launch a project to develop its own clinically validated wearable device.

Challenges and subcontracting

However, despite obvious benefits to utilising telemedicine in a clinical trial setting, many CROs do not have the technologies capable of Health Insurance Portability and Accountability Act (HIPAA) compliant video calls, the experts said.

It is unlikely many CROs would develop technologies capable of capturing and storing video calls or other remotely collected patient data in a HIPAA-compliant way, Kimball said. The second CRO executive added challenges to building such a platform is data protection legislation which varies from state to state. Kimball said subcontracted third parties would be more likely to provide such technology to CROs.

Third-party service providers working in telemedicine in the general healthcare (nonclinical trials) setting include Teladoc (NYSE:TDOC), MDLIVE, American Well, HealthTap and Doctor on Demand.

Shapiro noted despite Clinipace's aforementioned earlier interest in telemedicine in clinical trials, it is not yet pursuing it since there are no FDA regulations for use in this setting, only for the real world. Many CROs would likely need at least an FDA draft guidance document on telemedicine use in clinical trials before pursuing the matter further, Shapiro and a clinical technology service provider executive agreed.

Furthermore, telemedicine reimbursement is still relatively new in the real-world setting, hence it is not yet well-validated, Shapiro said. Once validated in general healthcare, sponsors may be more comfortable to consider its use in clinical trials, he said. CROs could look to provide telemedicine as part of real-world studies on drugs post approval, however, Shapiro noted.

Another challenge to the growth of telemedicine in clinical trials is the navigation of varying state laws - such as those over shipping clinical trial products - experts said. Dispensing clinical trial products is not permitted via mail in some US states, Shapiro explained, and patients may still have to collect drugs from sites.

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Email Analyst

Doctor licensing being segregated by state is also an issue for telemedicine visits, since a doctor licensed in one state could not treat a patient from another state, experts previously told this news service.

by Natalie Morrison in London

About Natalie Morrison

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