All Things Digital

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With a new year ahead of us, Abraham Gutman takes a look at the current technology available to pharma, and what it will be able to do in the future. Will clinical trials move closer to zero delay in 2016?

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Once again, a technological revolution is about to transpire. Just a decade ago, moving big, complex medical imaging files from one location to another was a major clinical trial advance. Around the same time, the International Committee of Medical Journal Editors also made trial registration a conditional requirement for publication (1). Due to these innovations and others, so much more can be done as an industry today – from compliance automation and quality control technology, to patient acquisition and management. And just as past technological advancements have had a lot to do with current progress, future ones can help companies improve in areas where there is still a lot of room for growth.

Clinical trial regulations have evolved tremendously in 10 years; however, today trials still take too long, data is still lost or corrupted, and patient recruitment challenges remain. Nonetheless, this year will undoubtedly introduce a host of new advances that will get closer to a place where compliance is simpler, participation is easier, and results are more predictable and structured. The industry's hunger for and adoption of new technologies is endless, and the following areas are a few that are worth keeping an eye on in 2016.

Telemetry Data and Devices

When the average consumer thinks about a wearable device, a common association might be the Apple Watch, which connects important data, phone calls, notifications and music to the wrist, in real time, in a discreet way. Anyone looking to amplify their health and fitness regimen will likely think of a Fitbit Charge, Garmin Forerunner or a variety of other cost-effective wearable devices that monitor health data and feed that information into a smartphone.

That is not all there is to wearable devices, however; they have the potential to become part of an array of new

technological tools to aid medical research, especially in clinical trial processes. Nearly 300 clinical trials are now using wearable devices according to the National Institutes of Health's records (2) – a promising but still incredibly small number in comparison to the number of trials taking place around the world.

The ultra-thin wearable patch developed out of the University of Illinois at Urbana-Champaign for example – which measures a patient's blood flow and offers critical information about health biomarkers (3) – has the potential to help physicians constantly monitor trial patients, providing immediate results within a trial, and further reducing delays in data collection. The ability to collect more data unobtrusively may help reduce subject attrition. The challenge lies in what exactly researchers, trial managers and medical professionals do with the data to make an impact on clinical trials.

Increased Patient Engagement

While doctors and researchers may lead the use of wearables in 2016, successful implementation of such devices ultimately requires interest from the patient's side. Fortunately for makers of wearable devices and doctors eager to utilise them, public consensus is positive. According to the PricewaterhouseCoopers' Health Research Institute, 56% of US consumers believe that average life expectancy will grow by 10 years because of the increased monitoring of vital signs that wearables offer; 46% of US consumers believe wearables will decrease obesity rates (4).

Wearable devices have the potential to provide a new level of engagement for clinical trial participants. Similarly, online communities such as www.patientslikeme.com can empower patients to determine the kind of research in which they want to participate, opening a new realm of patient-driven recruitment. This open flow of communications is likely to positively impact trial registration and encourage subjects who are in need to voluntarily reach out to the research community for help.

Human-Machine Interfaces

Another exciting trend that will continue to progress is the tighter integration of humans and machines. This integration will play out in at least two ways: collaboration and implants. The collaboration area, fuelled in a large part by advances in artificial intelligence (AI), will see robotic helpers learn to infer the intent of patients with limited mobility or ability to communicate, thus reducing the effort these patients have to make in order to have successful interactions with the world. In its simplest form, this may mean that a robot will get a command to fetch an object, without the person having to explain or describe all the steps necessary to locate the object, travel to the object, grasp it, travel back and release it to the patient. With powerful inference capabilities, these robots will be fully operational extensions, in both a physical and possibly sensory way, of patients who would otherwise be unable to care for themselves.

The implant area brings with it a variety of ethical questions. Earlier this year Dr Phil Kennedy, a Neurologist, took the exceptional step of undergoing surgery and getting a colleague to implant electrodes in his brain so he could carry out his own experimentation with thought-directed interfaces (5). As the functioning of the brain is increasingly being understood and signals generated by thought are beginning to be interpreted, the range of possible inventions opens up exponentially. With thought-controlled interfaces, developments like exoskeletons helping quadriplegics and interaction outlets for patients with advanced amyotrophic lateral sclerosis are suddenly within reach.

Both AI and implants are predicted to play a vital role in the clinical trial realm. These may emerge as treatment platforms, drug delivery mechanisms or technologies to help patients benefit from radically advanced, complex drugs and devices.

Genetic Engineering

An emerging area with the potential to disrupt disease control is genetic engineering fuelled by 'easy' gene editing techniques. This is, of course, as frightening as it is inevitable. Earlier in 2015 saw the $700 Amino home kit enabling people with slightly more than a basic understanding of chemistry

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and genetics 'play' the gene editing 'game'(6). And only recently, the FDA approved the first genetically modified salmon for human consumption. In this particular case, one of the modifications – making the salmon sterile – ensures that future 'Frankenfish' cannot escape and reproduce.

Another experiment involves editing the genes of milk-producing cows to ensure they do not have horns (7), which are typically dangerous to the humans that milk them. But perhaps the biggest disruptor in this area is CRISPR (8), which makes it more cost-effective and straightforward to carry out certain gene edits. We are not quite at the level of 'search and replace', but it seems likely that science is headed that way.

Without Delay

The industry needs to place emphasis on continued innovation and entrepreneurship; delays and mistakes should be avoided in the process. It will not come as a surprise if these technologies and services have an impact on the clinical trial industry in 2016 and beyond, though it will require a widespread effort to create lasting and significant change. With the help of some of these technologies and others yet to be invented, zero-delay clinical trials may no longer be a distant concept.

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About the author

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