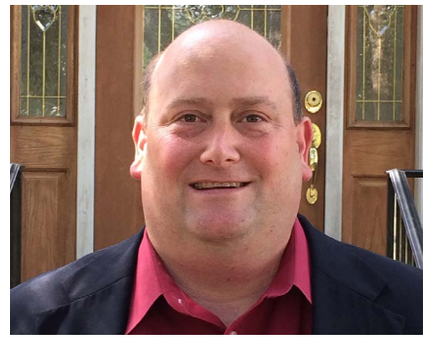
Published in June 2018
PharmaVOICE

Is Your eClinical System a Mixed Tape or a Playlist?



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Just a decade ago, the most advanced option for listening to music at home was a large stereo system made up of a jumble of separate components, all with specific functions, from a half-dozen brands. Not only were these stereo systems bulky they were also expensive, complex to set up and run, only able to play music you owned at home, and unable to handle new formats without the purchase of yet another piece of equipment.

How things have changed. Today all you need to listen to music is Alexa. Alexa can play just about any song you can think of, just by asking her using ordinary language. It's an astonishing transformation — we've replaced a static, complex, multi-brand collection of components with a single, modern and dynamic technology platform with intelligence in the cloud.

That same transformation is happening in the life-sciences industry right now. In response to the rapidly changing clinical research and development environment, new platforms are emerging that support every aspect of the clinical trial lifecycle from start-up and conduct, to close-out and post-marketing, replacing outmoded point solutions that companies cobbled together from different technology or service providers. Propelling this evolution was the pain and hassle caused by the fact that these components were scattered across different clinical trial functions, each stuck in their own silo and not built to operate together. "After-market" modifications by the users, in the form of complex system customization and forced plumbing between the point solutions to try and connect them, has only added to the problem. Needless to say, the time has come for a completely new approach to the way technology supports clinical research and development.

A Unified Clinical Platform Approach to Clinical Trial Management

This notion of a completely reimagined, unified clinical platform represents an enormous leap forward from the last generation clinical trial management technology. Like the old stereo system, most clinical trial systems forced you to buy, learn, and support hardware and software from multiple vendors. Each with different interfaces that required the same data be entered over and over, creating redundancy, inefficiency, and introducing the potential for error, and ultimately, risk. Like that old stereo system, old clinical trial technology is falling behind demands around speed, cost, and flexibility because its design and complexity preclude rapid innovation.

While some attempts were made to build linkages among those components and move them to the cloud, the resulting solutions were more like the "universal" remotes retro-fitted for those complex stereo systems — you could link the components together but once one component needed updating, you'd need to reprogram and update the remote. These remotes and stereo systems were not purpose-built to adapt to innovation, nor were they easy to manage and maintain. Similarly, while it seemed like integrating multiple solutions for various parts of the clinical trial process would streamline clinical development, it turns out that it created more inefficiency and challenges. Infrastructure and IT costs continued to climb as more departments required additional pieces of software to meet changing industry needs or when one component needed an upgrade and was no longer compatible with the others. Additionally staff needed to be trained on, and equipped to use multiple systems and interfaces. The result; stretched IT departments struggling to support a complex array of technologies, growing expenses, and disruption to the clinical trial process due to this piecemeal approach to development.

Like the Alexa technology, a purpose-built eClinical platform takes a completely different approach. A truly unified eClinical platform offers common features and functions that support multiple processes across different capabilities, and enables one-time data entry that provides a single source of truth that can be used throughout the clinical trial lifecycle. This approach makes it easy to incorporate updated standards, formats and requirements. Like all other industries, the life-sciences industry is also looking to move their technology to the cloud. They recognize that, by having their technology hosted in the cloud, the complexity of management and support is removed and user operations become straightforward and simplified. Instead of worrying about making the technology work, clinical research teams are able to focus on what matters most — trials and outcomes.

Advantages of eClinical Platforms

These eClinical platforms reduce IT infrastructure costs, let companies manage the burgeoning stream of data from both sites and mobile devices, maintain compliance with changing safety regulations, and incorporate the technologies clinical researchers and sponsors need, more quickly and easily. This increased speed, flexibility, and cost reduction is vital to meeting new expectations in clinical development. Additionally, a SaaS-based, eClinical platform enables the industry to address today's clinical needs, while being ready to adapt to new developments and innovation.

Consider that Alexa is constantly being updated to do things you never imagined possible when you had that old stereo. She can tell you who's playing drums on a song, recommend similar artists, find out when your favorite band has its next concert, purchase tickets, tell you what the weather will be that day and make a dinner reservation for you before the show. That's because, as a cloud-based platform, innovative services can be added via the cloud and delivered via the same device, quickly and easily without disruption to the user experience.

There is increasing pressure to reduce the time it takes to bring a drug through development to submission and ultimately approval, with the average cost pegged at $2.6 billion. At the same time, advances in science like genomic medicine demand the handling

and analysis of enormous data sets; the proliferation of eSource data — from mobile devices and apps, EHRs and non-CRFs — is also increasing rapidly. Patients themselves are becoming more active in clinical trials as participation becomes more of a virtual experience with the introduction of siteless trials and wearable devices. Safety regulations are becoming more complex and stringent. Finally, there's a growing need for consistent, real-world data that can be used on a global basis for everything from finding participants and monitoring compliance, to reporting adverse events and more.

Embracing a Modern Technology Mindset

For all this to happen, life-sciences companies need a new, modern technical environment to support their clinical research efforts. Interoperable tools will address these issues to help speed the development process, and ultimately bring life-saving and life-changing therapies to market faster — in some cases, upwards of 50% faster. Most importantly, by creating a more seamless process, clinical development teams and investigators can focus their attention on patient needs rather than navigating cumbersome, manually rigorous technology.

That old stereo may still work — at least for now — but once a platform something like Alexa becomes readily available, few people would want to go back to the old technology. Similarly, once you switch to a purpose-built eClinical platform, it will be hard to go back to those old, bulky, hard-to-maintain, siloed systems. When you can focus on the trial and the patients, instead of the systems supporting the trial, you can focus on bringing life-saving treatments to the market, faster. PV

Oracle Health Sciences *provides the only eClinical platform made up of best-of-breed solutions powered by the #1 data and cloud technology in the world. With Oracle Health Sciences, life-sciences organizations can manage and unify all elements of the clinical development lifecycle in a safe, secure, and compliant manner, while also being open, collaborative and adaptive to change.*

For more information, visit oracle.com/healthsciences.