

## ***Technology Trends that will Transform Clinical Trials***

by Craig Wigginton, *DATATRAK* Technology Advisor

---

The last major technical evolution in clinical trial execution was moving from paper-based processes to electronic data capture. This next phase of transformation will be another quantum leap forward – and equally disruptive – once regulators get a solid understanding of what it means and how to manage it.

### **Technology Transforming Industries**

Industry after industry, there are many examples of how hyper-connected consumers and social media are changing businesses and forcing entire ecosystems to adapt to the new paradigm. Long gone are the days of CD's - iTunes and the iPod have been the crushing wave that displaced the music industry. Netflix was the tsunami that wiped Blockbuster off the map. The list goes on – and technical evangelists will be able to map the rise and fall of these technology titans with perfect 20-20 hindsight as the years go by.

These technology evolutions, or revolutions, tend to come in waves as consumers adopt technologies and industries try to adapt and respond to the shifting paradigm. The prevalence of WiFi connectivity and almost unlimited bandwidth supporting our mobile computing platforms – yes, those things we call 'phones' – is drastically changing the way we communicate, the way we shop, and the way we work. Everything is different now. The drug and device development industry is set for dramatic change in the years ahead, to realize some real time and cost savings. Those that are able to seize the opportunity made possible by this new digital economy will lead in productivity, reducing the cost to deliver meaningful treatment to the world. How will your organization leverage these technologies to accelerate the delivery of vital cures to market?

The clinical trials industry is long overdue for a tidal wave to come through and lift the technical sophistication of the segment and the pressure is building for that exact situation in the coming years.

The FDA is already making strides in publishing recommendations on the use of social media. Many companies are jumping on the 140-character bandwagon, including Abbvie and Pfizer, making use of their Twitter accounts to engage patients and engage the clinical community. But moving beyond a simple Twitter feed into a comprehensive social media strategy to engage their target audience is something very few companies are doing well, if at all.

Every week we are reading about pharma companies and the FDA trying to get their arms around the use of social media – trying to find a way to harness the power of the medium while keeping the best interest of the patients, trials and clinical research system in check. The pressure continues to build and eventually the flood waters will burst through and patients will begin adopting these social

### ***Technology Trends***

- *Mobile*
- *Social*
- *Cloud*
- *Big Data*

media platforms as they push to gain critical support and information related to clinical trials, whether its availability, symptoms, placebos or outcomes.

According to a recent blog post written by Michael Simon, the director of analytics for President Obama's campaign in 2008 and co-founder of HaystaqDNA, "It's estimated that 90% of the world's data was created in the past few years, and the computing power needed to harness that information is growing quickly to keep up. This rapid change means it's important for policy makers to begin thinking now about the appropriate role of government in the field. Advancements in technology aren't going away, but are only just coming to maturity — and we need to quickly figure out how to create a regulatory environment that balances privacy concerns with encouraging innovation that can unlock the incredible potential of data analytics."

At this state of the technology industry, every company must be studying how **Mobile, Social, Cloud** and **Big Data** will revolutionize – or marginalize – their business. The explosive growth in these areas will have a dramatic impact on the world of drug and device development, and time will tell if regulatory agencies, CROs and Pharma can respond quickly enough.

## Mobile

### *Expansion of Mobile Phone Capability*

It is now estimated that the number of smartphone users will reach 1.75 Billion worldwide in 2014. As technology evolves to power the smartphone, from apps to visual conversations, like FaceTime, the power to track and analyze data expands. The smartphone of 2012 had more computer power than that available to Apollo 11. Yes, that phone in your hand has more power than NASA had at its disposal to get a man on the moon. And we all recognize that technology has continued to evolve, some would say exponentially, in just these last two years.

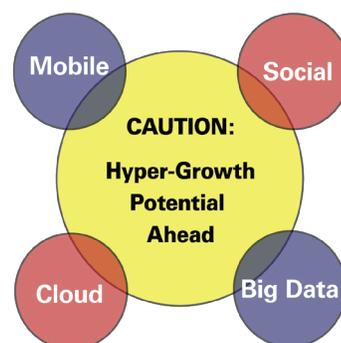
When smartphones added GPS, it unlocked enormous value on the handheld platform, which effectively put an end to yet another industry – printed maps. However, that is just the tip of the iceberg, because the real power of the platform is for all those millions of users to switch from being map readers to being map producers and validators – with every GPS-tracked mile, we are now able to layer in real-time input from mobile devices and users all over the world about road conditions, current vehicle speed and the location of potential traffic issues.

### *Wearable Technology is defining the next wave of mobile health*

For the clinical trials industry, the rapid grow of low-cost wearable health monitors for the consumer market is a fantastic avenue for identifying potential patients and gathering huge volumes of data spanning years of an individual's life. The game changer is the ease of data collection – just snap on a wristband or tag onto your clothing and you are collecting data. In the last year, several new entrants have brought products to market that are stylish, highly functional, and fully integrated with online portals for reporting and analysis. Misfit Wearables, for example, is delivering a small wearable disc attached to your clothing that makes it easy for consumers to wear the device 24x7 – capturing all the vital data needed to create accurate maps of activity and exercise. FitBit, on the other hand, utilizes a flexible wristband to track your movement. Both systems provide a tremendous number

### **Expanding Mobile Capability**

- 1.75 Billion Smartphones Globally in 2014
- Growing availability of Health-Related Apps
- Wearable Technology



of features in a small package.

Leveraging the Bluetooth connections and eventually Near Field Communications (NFC) on the mobile platform will enable these micro devices to gather valuable data from millions of consumers - and patients - from around the world without costly proprietary infrastructure.

Mobile Health Monitoring is another facet of the health-related data explosion that could also bring significant insights to clinical research organizations as they try to find ways to gather data on subjects without bearing the cost of expensive monitoring systems. For example, Apple was recently awarded a patent for ear buds that can monitor the vital signs of the person wearing the device. This is significant because it allows users to collect detailed data on their heart rate and other vital signs while exercising to their favorite music. Patients are purchasing these applications and hardware – cataloging millions of data points each year that are waiting to be harvested and analyzed by biostatisticians and clinical research teams. There are hundreds of applications and devices in the market now that are able to track heart rate, blood pressure, temperature, sleep patterns and even snoring during sleep. With all this data coming from each patient, how will that change the landscape of data analysis? And will regulators be able to define safe boundaries and data blinding to leverage this data to accelerate delivery of tomorrow's cures?

## **Social**

*Social Media is already influencing clinical trials – we are probably farther behind than we think*

Self-measurement and tracking of personal habits will surely provide clinical researchers much needed data about the health history of patients. However, the next frontier for pharma companies and clinical research organizations is to tame the vast landscape of social media. Facebook has 1 billion members and Twitter is surpassing 500 million users and the numbers continue to rise at a rapid rate. As more patients turn to the online communities for support and information about clinical trials available in their area, companies need to find a way to respond within the scope of the current rules and regulations.

Technology start-ups like Treato, for example, are attempting to help pharma companies make sense of the data being published by millions of patients across these social media sites by delivering Big Data analytics to provide rapid insights that would otherwise take years to decipher.

To capture real-time patient comments from social media, Treato uses a combo of Natural Language Processing algorithms, patient language dictionaries and Big Data analytics, according to the company. The approach has enabled the company to gather and analyze 1.3 billion conversations about 24,000 drugs and conditions from thousands of websites.

*Cure Collaboration is shaping social media in the clinical realm*

Crowdsourcing and social media go hand in hand, especially when it comes to getting a large population to publish their experience with a certain product or service. Several social media companies have recently begun taking that notion

## **Expanding the Use of Social Media**

- *Analyzing Posts with Technology*
- *"Cure" Collaboration*
- *Role of Regulatory Agencies*

one step further – focusing on health-related discussions and treatment-specific forums that allow users to rank their outcomes and feelings toward the procedure and/or treatment options.

One online treatment collaboration site, CureTogether.com, has crowd-sourced data on treatment effectiveness on over 600 health conditions. The content and format of the information allows almost anyone to jump online to take a more active role in their treatment. Clinical trials now have a focused channel to a great number of patients seeking solutions to specific medical conditions; how trials leverage these channels to engage a focused set of patients for a study has yet to be seen. CureTogether.com was recently acquired by one of the leading genome sequencing companies, 23AndMe.com; the potential for studying treatment effectiveness based on genome differences could further accelerate data analysis to understand the interaction of newly developed compounds with certain DNA sequences. This is truly an exciting time to be able to match human DNA with treatments in order to study safety and efficacy of a drug.

With the proliferation of treatment effectiveness data being available online and patients in clinical trials striving to find out if they are receiving the placebo or the drug through social collaboration, this presents new challenges to organizations managing clinical trials. The answer is not to wait until a group of patients have to be removed from a study – companies must act now to organize their strategy for how to deal with the new reality.

### ***Genome Sequencing***

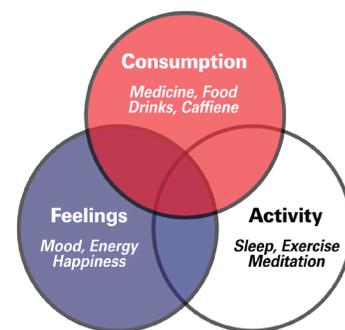
While the landscape has changed in the genome sequencing market over the past several years, the fact that costs for test kits continue to fall means more people have access to this amazing technology. The DNA sequencing company 23AndMe.com recently transitioned to focus on DNA-based ancestor tracing instead of health risk identification, but other companies are charging ahead to achieve the goal of mapping the entire human genome for \$100. This is an astonishing goal considering in 2007 it cost around \$1 million to map James Watson’s DNA.

The Federal Government just announced a \$25 million program to map the genome of newborn babies – allowing researchers to immediately see how these babies would metabolize medicines, how they will react to certain foods and what childhood diseases they may be susceptible to. Having that level of information during the first few years of life could dramatically change the landscape of children’s health.

### **Cloud Computing**

*Cloud Computing is not the future, it is the present*

If you own a smartphone, chances are very high that you already have your data living in the Cloud. For enterprise companies, the definitions and boundaries get more complicated as more and more companies make claims about being cloud-based services when they are really highly-customized, hosted solutions. If Facebook had tried to customize their system for each user of their platform, they would not have been able to ramp to more than 1 billion members in such a short period of time.



Cloud computing, in simple terms, means you access software or data across the network when you need it, on demand. Any enterprise looking at purchasing software or services in today's environment must at least consider the Cloud-based option, as long as it doesn't require customization. The best Cloud-based solutions in the market today (actually, in any market) are scalable, secure, fast and **configurable** – that's right configurable.

In the clinical trials industry, enterprises need to carefully evaluate vendors to determine if every installation is a customized deployment or if it is truly a cloud-based solution that will enable your business to scale.

### *Benefits of Cloud Computing*

One of the most exciting aspects of Cloud computing is the way it is transforming businesses that traditionally were held back by underperforming IT organizations for many years. At last, business leaders can rapidly deploy the world's finest software applications without spending weeks, or even months, wrestling with internal IT committees that have difficulty communicating with business leaders about the true needs of the departments.

Now that Cloud computing has been in the mainstream for several years, we are starting to see a natural separation of vendors providing services along the continuum of cloud-enabling technologies, from delivery of the entire software solution down to simpler solutions offering only the bare infrastructure in a secure Cloud environment.

Leading Software-as-a-Service (SaaS) vendors such as Salesforce.com, WorkDay, DATATRAK, and Seibel, all provide the entire stack of technologies and are experts in their domain – covering the entire application software, supporting platform and underlying infrastructure. These vendors provide customers with a highly tuned, highly optimized environment that can be managed by a set of service level agreements. However, not all companies want the entire stack – and that is where new entrants have been making headway in the market.

For companies looking for alternatives to efficiently deploy legacy software applications, they need to look no further than cloud platform providers such as Apprenda, Amazon Web Services (AWS), Appistry, Force.com (Salesforce.com's platform division), and Microsoft Azure. These Platform-as-a-Service (PaaS) offerings provide robust service levels covering all the infrastructure and platform components required to get your software up and running quickly. If custom software is required to solve your business problem, Cloud deployment is still an option with a PaaS deployment.

If embracing the Cloud still seems too complicated due to custom software and complicated platform requirements, there are still options available. Vendors recognize the proliferation of legacy software in the industry and provide Infrastructure-as-a-Service (IaaS), which allows deployment of proprietary applications and server configurations on a Cloud-based set of infrastructure. Deploying software with an IaaS vendor eliminates many of the headaches related to integration between networking components, storage devices, and connectivity vendors. This type of deployment draws many similarities from all other Cloud deployments because the infrastructure is normally standardized and available to the customer on-demand. Web-based customer portals provide users with self-

### **Benefits of Cloud Computing**

- *Scalable*
- *Secure*
- *Fast*
- *Configurable*

provisioning of the computing resources, forcing customers to provision equipment in a standard way – increasing reliability and reducing variability across the deployments.

Most companies are looking for ways to cut cost and increase reliability of the solutions they provide – and adopting Cloud-based solutions should be a core part of the technology plan to achieve those goals. Whether you engage a SaaS solution provider with deep experience delivering configurable solutions or you engage a platform provider to accelerate the modernization of legacy applications, Cloud deployments are likely part of the answer.

## Big Data

If you believe Big Data is a fad that will quickly pass, I encourage you to think twice about the data revolution you are living in today. Big Data is changing everything and the pace of change in the world of big data is truly difficult to describe, as growth continues.

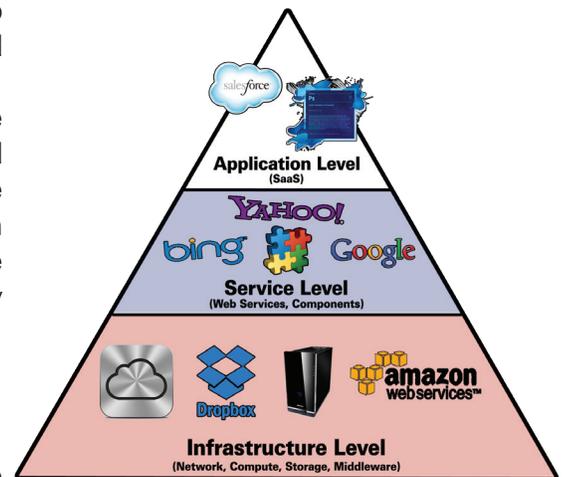
Estimates show that we have created 90% of the world's electronic data within the last two years and the rate of creation continues to accelerate. As an example, Facebook revealed its users have uploaded a whopping 250 billion photos, with 350 million photos added per day. Users on the popular social media site share more than 4 billion postings per day. What percentage contains data about how someone feels or their activity levels? While this content is not specifically tracked, read through your own Facebook posts; it's safe to say a few million a day relate to physical and emotional state, and activities, from running, golfing, or watching movies. Those are not exactly electronic case report forms, but it also does not require a site visit or employee time to collect the data.

In the clinical research industry, a consortium of pharmaceutical companies has formed a not-for-profit effort, Project Data Sphere, to share and analyze de-identified, patient-level data from late-stage comparative studies to be analyzed. The hope is that with access to historical clinical trial data more efficient clinical trials can be designed, reducing the cost and accelerating the speed of finding meaningful treatment. Leveraging this dormant data is one example of how the clinical research industry can use the powerful techniques used in Big Data analytics to actively address the safe acceleration of clinical trials.

### *Quantified Self – The Big Data Jetstream for Health Care*

The intersection of Mobile, Cloud and Big Data computing has enabled a unique opportunity that is likely going to be a dominant piece of our individual lives for many years to come – the Quantified Self movement. Many online blogs and application developers in the Quantified Self space will emphasize this junction as a movement due to the loyalty and commitment the participants have toward the cause. The tie-in to Big Data is staggering as you think about the volume of data being generated and the potential liabilities of making decisions based on data gathered from hundreds of anonymous and distributed sources.

A few online searches will help you realize what the craze is about – collaborating with your peers online to improve the quality of their life by tracking what matters. Thanks to mobile applications, the old saying – you can only manage what you measure – now means we have no excuse when it comes to those New Year's



### **Big Data Emerging Efforts**

- *Project Data Sphere*
- *Quantified Self*
- *Mobile, Social, and Big Data Convergence*

resolutions. The Quantified Self movement has exploded in popularity over the last several years with more than 100+ applications available for download from the Apple AppStore alone. Regardless of which mobile platform users are carrying, there are applications for tracking everything related to daily consumption, including food, drinks, vitamins, medicines, smoking; daily activities including exercise, sleep, meditation and laughing; and your mood, including energy level, stress, mood or happiness.

For clinical trials managers, Quantified Self brings tremendous possibilities for data collection and correlation analysis based on hundreds of thousands of data points collected directly by patients. It also brings challenges because patients are looking to avoid the overly complex and costly healthcare system by taking control of their own health status via self-quantification, measurement, and analysis. The wealth of historical data being collected every day – often long before a patient will ever engage in a clinical trial – could be as powerful as EMR data for patients that diligently track health status.

For patients in a clinical trial, the potential to capture nearly unlimited data about their mood or daily food intake during the study by having the user snap a quick picture of each meal changes the landscape of data analysis for clinical trials – pushing the envelope of Big Data significantly over the next several years.

Big Data will have a tremendous influence on our lives in the coming years, hopefully used in conjunction with the mobile technologies, cloud platforms and social networks to accelerate delivery of cures for the next generation.

## **Summary**

In a few short years, the landscape of computing has changed dramatically and most industries are now starting to gain traction in utilizing the full capability of today's machines. With nearly endless wireless bandwidth, gesture-sensitive touch screens, and handheld form factors packed with accelerometers and GPS synchronization, the ability to capture data from any person or location in the world is seemingly unbounded. These exponential advancements in Mobile, Social, Cloud and Big Data will certainly continue, introducing new opportunities for clinical research, in traditional forms and ways we have yet to imagine.

The ability of the industry to adopt these advancements, and others we aren't even imagining, is the real question. Certainly a deeper understanding of the benefits, and pitfalls, of these technologies must be well understood and delivered not by technology experts alone, but by industry leaders who have a deep understanding of the needs of clinical trials and the technology. Without expertise in both areas, the true potential of technology to transform the clinical trials industry will be only partially realized.