

Revolution or Evolution?

Technology can disrupt conventional, long-standing practices in clinical trial management, which has historically been slow to adopt new technology and cloud-based services. With the industry now beginning to embrace these new methods, a technical evolution has begun

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The pharmaceutical industry is abuzz with visions of cloud-enabled services and new technologies that foretell a digital transformation of the clinical trial process. Recent industry conferences have focused on the 'virtualisation' of trials, forecasting patient-direct, 'visit-/site-less' approaches underpinned by strides in artificial intelligence (AI). In this worldview, a new generation of healthcare-grade wearable devices will feed a shareable, platform-agnostic 'Big Data' machine that revolutionises the world of drug development – or so many pundits say.

The vision of the future and the promise of speed and efficiency for drug development is exciting and awe-inspiring. However, the reality of Big Data, automation, and AI accelerating drug discovery will – and should – come as an evolution in clinical trials, not a revolution.

The key variable for effective technological transformation is the same as it has always been: ensuring the quality care and safety of human beings. Today, the spotlight on the patient burns even brighter than it did a decade ago. Patient engagement, rights, patient-centred strategies that focus on ease of implementation in new study designs, and the development of indication-based patient advocacy groups are all topics that dominate current professional meetings right alongside the latest technical innovations. The industry that took a decade to embrace electronic data capture (EDC) is now doing what it always does – reaching out to the future while looking back over its shoulder, maintaining a careful eye on the process lessons of the past.

Entrepreneurial vision truly shapes our future. While other companies were in the typewriter business, IBM leaped forward to define its business as word processing – the genesis of the personal computer. Amazon – launched in 1994 to bring e-commerce technology to sell books – has gone on to dominate other retail markets. The company with deep pockets recently spent \$13.7 billion to purchase Whole Foods, with plans to disrupt and dominate another market – grocery stores. Now, Amazon is looking at healthcare.

Roger McNamee, co-founder of private equity investment firm Elevation Partners, has speculated on the CNBC show 'Fast Money' that the apparent Amazon deal with Cerner, one of the world's biggest health tech companies, is a milestone for Amazon's intentions. He states that their

move is typical of their approach to disrupt industries, especially those that have been reluctant to fully embrace cloud-based services.

The magical allure of the new model represented by the Amazon deal is indisputable. Imagine having immediate access to a huge number of potential patients for trials and instant communication channels to recruit them. Clinical data would be transparent and trackable for centralised monitoring and risk-based management. Key performance and risk indicators would be automated. Variances from expectations for quality, compliance, and performance would be flagged for automated alerts.

The days of spreadsheets, manual tracking, and source document verification would be a memory – like the typewriters of yesterday. Clinical data could be streamed to phones, tablets, and desktops. Patient diary entries could be as simple as a discussion with Alexa, with remote visits through telemedicine aided by data-collecting robot-nurses. Can CROs compete with Amazon? Time will tell, but the vision is certainly revolutionary.

Initial Hesitations

Imagine the industry is poised at the edge of a cultural cliff, unsure of how long it will be here, balanced on one foot, wings spread and ready to fly. Historical performance favours those who bet that technological transformation will continue to evolve cautiously, two or three steps – maybe more – behind the technical capacity for change. Even today, spreadsheets and manual processes still abound despite the skyrocketing cost of clinical development and the urgency to reach market approval. Technology can, and will, help us achieve many of the goals of the pundits' visions. Only the timetables are at issue.

However, some technological goals – for example, the stated aim to fully replace human doctors with healthcare-provider machinery – will raise different questions and may arguably never be fulfilled. The contention stated at one recent professional conference that AI-driven diagnostics will be more accurate than diagnosis by human doctors has little sound scientific basis in an arena still recognised to be part science, part art. Ultimately, change will require a major paradigm shift in our fundamental understanding of holistic diagnostics.



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Many interactive response technology (IRT) and EDC vendors continue to embrace the principle of measured technical advancement in the development of systems and processes. IRT has evolved significantly within 12 years, and paper processes have been transformed with interactive voice response (IVR) phone-based systems. The transition to interactive web response leveraged the widespread adoption of the internet. The suite of tools enabled by web-based services accessed on computers and mobile devices fuelled expansion of IRT services and delivered greater ease of use for trial sites and patients. As expected, measurable efficiencies followed the correct application of technology to new processes. For example, the evolution from phone to web reduced the time required to enrol a subject from six minutes to a little more than a minute. This kind of achievement, exciting for its time, is now seen as amusingly modest as sights are set on bigger and better goals. This stepwise accomplishment is exactly the sort that will grow the industry to where it wants to be.

Many other IRT services have logically and systematically evolved over the past decade. These include:

- Diverse and sophisticated randomisation schemes
- Robust shipping and resupply options
- Individual site profiling
- Complex drug assignment processes
- Multiple drug sourcing strategies
- Advanced inventory controls
- Drug accountability and drug returns
- Temperature excursion tracking
- Real-time transactional integrations with EDC, electronic patient-reported outcomes (ePROs), clinical trial management systems (CTMS) and other platforms

- Authorisation controls to capture protocol deviations
- International flexibility in subject management

All this stems from a technology that, a decade ago, was expected to be made obsolete by the advent of EDC systems. Pundits were sure that IRT functionality would be absorbed as an EDC front-end. That revolution never occurred. Instead, IRT evolved in an orderly fashion to meet the new challenges of the day – a win-win for all concerned.

Today, the evolutionary holy grail is ‘eClinical’, the one stop shop that integrates all separate functions (eg EDC, ePRO, CTMS, etc) into one mega-platform for the execution of a clinical trial. The revolutionary holy grail might be called ‘eVirtual’ – a revisioning of the clinical trials process in a way that removes most of these functional distinctions. Can everyone gather in the cloud to do away with structured randomisation in favour of Big Data and real-world evidence, as some suggest? Can current drug assignment protocols be cut and achieve a wholly alternate drug management and delivery strategy?

Before leaping further into the cloud with more applications and patient data, careful examination of the critical variables in clinical trials needs to be undertaken – data ownership, data quality, chain of custody, data security, and patient consent and privacy considerations. The ‘fine print’ in agreements to host data in the cloud raises significant issues that are more suggestive of the need for evolutionary tactics than a call for revolution.

The necessary cautions also extend to the world of mobility. We live in a “BYOD (bring your own device)” culture – iOS or Android; mobile, tablet, or laptop; Amazon Echo or

Google Home. As we transition to more mobile applications for healthcare, classic concerns about the underlying capabilities, data security, and data ownership are amplified. What other applications are on the phone? Which ones have been granted permission to access the phone's contact list and use its camera and/or microphone? Blanket permissions to access data may make healthcare data available to other applications. Ownership delineations become blurry. Often, these applications run in the background, continuously accessing data that may be unknown to the users.

The promise of wearable devices in clinical trials is tremendous for clinical study endpoints, though data accuracy and verification remain primary concerns. Tracking drug compliance is a logical early adoption goal, with a number of sponsors now investigating technological ways of ensuring that a patient has actually ingested a given capsule at a given date/time (eg an embedded chip). In this realm, 'working the kinks out' will take time.

Before widespread adoption of patient data collection from wearable devices can be achieved for clinical trials, the issue of accuracy has to be addressed. For example, a wearable tracking device has been known to add significant steps in scenarios where it would not necessarily be applicable, such as when driving. Would this type of data be accurate enough for clinical trials? Beyond this, other variables exist such as does the place on your wrist on which you wear your device affect readings like the monitoring of a person's heart rate?

Slow and Steady

The general consensus that pagers would be replaced by mobile phone texting was too aggressive. A market for pagers still exists today, though it is smaller than it once was. In this industry, as noted earlier, the consensus in the 1990s that IVR would simply be taken over by EDC systems was similarly too aggressive. Today, EDC systems typically do not do the things that IRT systems do so well. By focusing on separate development paths, independent evolution of sophisticated functionality has been advanced in each realm. The separation between IRT and EDC has turned out to be a good thing in other ways; changes that can take three weeks in an EDC system can sometimes be done in a day in an IRT system, often at less cost.

The industry is not looking for disruption, always taking careful, incremental steps on the journey to increase the speed to market while reducing costs through efficiency. Paramount focus is turned to patient safety and the integrity of data. While marching along the roadways of innovation, IRT systems – and all systems – will continue to do all the things they do so well.

Vision Transformations

Vision is, by definition, revolutionary and necessary to chart a path that changes the world. According to industry analyst firm IDC, the top three companies in 1967, in terms of revenue, were IBM, AT&T, and Eastman Kodak. The top five in 2017 are Apple, Alphabet (parent company of Google), Microsoft, Amazon, and Facebook. The cultural changes behind these statistics would have been impossible to predict 50 years ago.

In the 1940s, Dick Tracy's watch captured the imagination of the nation as the coolest wearable device ever; in 2015, the wearable known as the Apple Watch was launched, and so it continues; Star Trek's handheld communicator may have inspired flip-phone mobiles, and the Star Fleet Communicator Badge was a handy wearable. Today, miracles and science fiction in healthcare technology include gene-based drug development and studies with an N of 1. Vision and innovation are a big part of what makes human life worth living.

However, real transformative change also happens over time. To put it another way, the answer to the question of whether change is evolutionary or revolutionary may be recast as follows: a critical mass of evolutionary change can result in a revolutionary difference. Seemingly radical changes may, in fact, be the result of many baby steps. It took years after IBM talked about word processing before the first personal computer was born, and more years passed before it became a pervasive business tool. Google started out as a search engine, Apple as a personal computer for tech geek hobbyists.

Jeff Bezos, the founder of Amazon, is widely quoted as saying that bold bets are experiments. The success of experiments is uncertain. Bold bets are driving today's innovations in healthcare. The justifiably conservative nature of the clinical trial industry will be watching the effects carefully as our industry continues to evolve.

About the author



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