E Pluribus Unum: Out of Many, One

As the modern world pushes towards consolidated technologies, it is increasingly important to address the inefficiencies already present in organisational siloes

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Drug development is a brutally competitive industry, with the total capitalised cost of bringing a successful new drug to market now exceeding US $2.5 billion, and, despite significant increases in R&D expenditure, returns are diminishing with experimental drugs gaining regulatory approval falling to one in 10 (1-2). Adding to this dilemma are the costs associated with conducting clinical trials, which have risen at a rate 7.4% higher than inflation (3).

Life sciences organisations are in a race against time to reduce the 'innovation gap' in drug development and costs and are exploring numerous ways to curtail development timelines and increase the odds of successfully bringing new treatments to market, cumulating in significant investment in eClinical tools (4). According to research conducted by the Tufts Center for the Study of Drug Development, investments are bearing fruit, with 80% of organisations who have invested in eClinical technology reporting time savings and 30% shorter cycle times in comparison to those with inadequate technologies (5).

The continued adoption of eClinical cloud-based solutions has resulted in a quantum leap in terms of automating manual processes and addressing inefficiencies endemic in clinical trial progress. Technology has become critical in the fight to reduce costs and the complexity of studies, however, it is not a panacea. Rather, it is a catalyst to providing the performance metrics needed to empower business intelligence (eg, benchmarking or descriptive, predicative, and perspective analytics), process optimisation, and efficient resource allocation, thereby improving proactive planning and aiding the breakdown of organisational siloes. This automation also serves to improve collaboration among stakeholders and is pivotal to modernising clinical trials, streamlining communications, and enabling real-time decision-making.

Unintended Consequences

Unfortunately, the rapid development of point solutions resulting from the automation of manual processes has led to unforeseen consequences, none felt more acutely than at the investigative site. Clinical research sites – the heart and soul of clinical trials – are now awash in eClinical technologies, with research reporting that sites are now using, on average, 12 different systems to capture clinical study data (6).

This onslaught of point solutions comes at a time when sponsors and CROs are looking to strengthen collaboration with sites via the continued adoption of technology, with the promise of making it easier for them to participate in clinical trials while enhancing transparency, quality, and efficiency. Unfortunately, there is little evidence that they are helping in this regard or enabling clinical trial performance (7). Worse still, this situation is contributing to the technology burden on sites and the one-and-done syndrome that plagues the industry (8).

Site staff responsible for study activation and conduct have unwittingly been cast in the role of technology specialists, while sponsors and CROs have unintentionally created and contributed to "a fragmented ecosystem of different software, vendors, and processes – one or more for each 'silo' that exits within the sponsor/CRO world." (9)

eClinical Technology Entrenched in Siloes

eClinical applications are often budgeted and deployed according to functional groups within sponsor/CRO organisations. 'Aftermarket' modifications by users, in the form of complex system customisation and forced plumbing between point solutions, have only added to the problem (10). Recent research shows there is no slowdown in sight, as a significant number of integration projects are underway, planned, or have been completed, with the most important initiatives of these projects cited as being "improved study quality," "faster study execution," and "greater visibility into study status(es)." (11)

This cobbled-together patchwork of eClinical systems from different technology or service providers, each with their own interface and login requirements (for the same data to be entered in over and over again), has created unnecessary redundancies, inefficiencies, and the potential for error.

Fortunately, technology provides the opportunity to rethink the inefficiencies of organisational siloes. Some stakeholders want to move away from vertical siloes and start thinking 'horizontally'. This method uses automation

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and workflows to integrate operational data across all functions, making it easier to extract meaningful insights from those data (12). Some also believe that bringing interdependent functions together using technology and critical teams will help navigate the highly complicated global regulatory maze (13).

Dismantling Siloes by Unifying Technology

The eClinical industry has reached a convergence point, a natural progression for these point solutions to become unified and blur boundaries as they have evolved. The omnipresent smartphone provides a perfect analogy, comprising different applications and functions (eg, phone, web browser, palmtop computer, games console, camera, mp3 player, etc) conveniently provided and interconnected on one device and which were previously disparate technologies.

A unified platform providing functionality based on a role is a logical progression in eClinical technology development, with the majority of sponsors/CROs preferring and supporting this evolution (11).

It is time to dismantle this eClinical Frankenstein with a single, unified environment that supports the entire clinical development lifecycle from bench to bedside (14). Only by removing the blinders inherently created by the current environment of independent point solutions can the possibilities be seen.

A truly unified eClinical platform would offer common features and functions that support multiple processes across different capabilities, providing what is needed, when it is needed, to those who need it based on role, thereby eliminating unnecessary integrations and duplicate data entry. One-time data entry would ensure a single source of truth that could be used throughout the clinical trial lifecycle. This approach makes it easy to incorporate updated standards, formats, and requirements and aids in helping to break down the inefficiencies associated with organisational siloes.

The industry is at the crossroads of change. Life sciences organisations recognise the need to modernise their technology and processes to address entrenched bottlenecks in the clinical trial continuum, but, at the same time, they are struggling to break free from the 'status quo' which blinds them to opportunities. Research shows the momentum to source all eClinical applications from a single vendor – a one-stop-shop philosophy – is growing, with 42% of respondents having adopted this approach and 62% indicating that this would be their preferred choice (11).

When asked how believable it is that one technology or service provider could provide industry-leading applications across the clinical trial continuum, 70% of respondents stated that it was moderately to extremely believable.

These findings are indicative of an industry-wide drive toward a unified clinical model, supporting greater collaboration and insights across the end-to-end processes and systems which constitute the clinical trial continuum. (15).

Detractors and Resistance to Change

As the arduous task of dismantling siloes begins, there is a growing recognition that technology is critical. A unified platform spanning the clinical trial continuum, with support from top management, will become paramount to overcome the innovation detractors sowing the seeds of fear, uncertainty, and doubt. This contributes to the technology risk aversion we see in pharmaceutical industries today.

Perhaps the greatest challenge that lies ahead is change management. mHealth technology is a timely example that holds the potential to disrupt data collection processes, ease the burden on patients, speed patient recruitment, and generally reduce sponsor burden in clinical trials. However, adoption of these technologies continues to be slow, despite the perceived benefits (16). In research conducted by SCORR Marketing and Applied Clinical Trials on mHealth technologies, when asked which group was the most resistant to adoption, 38% of respondents pointed to pharma companies, with only 22% citing clinical sites and 15% citing patients.

Driving incremental but not dramatic change may explain why organisations, especially large, complex pharma

companies operating in a highly regulated environment, are slow to adopt truly innovative IT solutions with the potential to drive down costs, reduce cycle times, and, ultimately, get new drugs to the market faster. IT departments look for ways to streamline current workflows rather than fundamentally disrupt them. For instance, Microsoft Excel is still predominately used for site selection, as well as initiation phases of starting clinical trials, with IT managers looking to provide greater incremental value (with eRooms, email distribution groups, shared drives, etc) without fundamentally changing the underlying workflow process (17).

Driving Strategic Imperatives

According to research, 66% of respondents identified challenges in adopting new clinical systems with "internal resistance to change," "lack of executive support for change," and "unavailability of budget to pursue investment in technology" ranking highest, indicating that specific projects suffered from lack of executive support (11).

Technology adoption is not easy, but opportunities abound for those organisations and leaders willing to challenge the 'status quo' and bring about significant change (18).

While there may be no silver bullet, there is a silver lining: by driving industry awareness, supporting change agents, promoting the success of those organisations striving for real change, and realising the benefits, early adopters will achieve efficiencies and reset expectations for the industry as a whole. The importance of change being driven by upper management cannot be overstated.

Executive buy-in provides the critical impetus and strategic insight to align with the organisation's goals for development of better therapies more quickly. Without this direction, efforts to jump-start overall performance optimisation tend to flounder. Research suggests that organisational issues become strategic and of interest to upper management once they believe it has relevance to performance (19).

By embracing a unified eClinical platform, accompanied by support from key decision makers, it would be possible to move the needle on process changes and increase the likelihood of greater site engagement in studies, more predictable cycle times, better adherence to study budgets,and audit readiness – underscoring the power of unification, the 'power of one'.

References

1. DiMasi JA *et al*, Innovation in the pharmaceutical industry: New estimates of R&D costs, *J Health Econ*: pp20-33, 2016
2. Visit: phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf
3. Visit: www.cmaj.ca/content/cmaj/180/3/277.full.pdf
4. Visit: www.prnewswire.com/news-releases/the-global-clinical-trial-it-market-is-expected-to-grow-from-263-billion-in-2016-to-429-billion-in-2020-at-a-compound-annual-growth-rate-cagr-of-more-than-130-300599440.html
5. Visit: go.oracle.com/LP=80941?elqCampaignId=203519
6. Site experience with technology solutions supplied by sponsors/CROs, *CenterWatch*, 2016
7. Visit: myscrs.org/learningcampus/white-papers/6621
8. Visit: www.clinicalleader.com/doc/one-and-done-how-bad-is-the-pi-turnover-problem-0001
9. Visit: www.appliedclinicaltrialsonline.com/stop-expecting-sites-love-technology-just-because-it-s-new
10. Visit: www.pharmavoice.com/article/2018-06-eclinical-system
11. Visit: go.oracle.com/LP=80980?elqCampaignId=203523
12. Visit: www.outsourcing-pharma.com/Article/2017/01/17/The-rise-of-technology-enabled-clinical-research-companies
13. Visit: www.strategyand.pwc.com/report/critical-makeover-pharmaceutical-companies
14. Visit: www.clinicalinformaticsnews.com/2018/03/05/eliminating-silos-dismantling-frankenstein-clinical-rnd.aspx
15. Visit: www.clinicalleader.com/doc/study-startup-technology-investment-pays-off-0001
16. Visit: www.clinicalleader.com/doc/report-pharma-is-most-resistant-to-mobile-technology-use-in-clinical-trials-0001
17. Visit: www.appliedclinicaltrialsonline.com/eliminating-three-evil-es-starting-clinical-trials
18. Visit www.clinicalleader.com/doc/why-is-it-so-difficult-to-implement-new-technologies-0001
19. Dutton J and Ashford S, Selling issues to top management, *The Academy of Management Review* 18(3): pp397-428, 1993

About the author

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