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Overcoming the innovation malaise

By Craig Morgan

Innovation is often cited as the "key ingredient" by organizations striving to sustain an advantage in the increasingly competitive global marketplace. The pace of technology change is relentless, with those who don't embrace emerging trends often paying a hefty price. Simply "doing the same thing better," however, *is not enough*.

Technology adoption—particularly in highly regulated environments—is a complex issue that deserves careful thought and consideration. Innovation detractors comfortable with the status quo often sow the seeds of fear, uncertainty and doubt, which contributes to the technology risk aversion we see today in pharma.

Life science organizations adopt new technologies all the time; high-throughput screening, continuous manufacturing, targeted therapies, etc. So what's the problem? They spend vast amounts of money and effort in the drug discovery process but will skimp, postpone or completely abandon anything to do with new software that could significantly improve the latter stages of drug development—that is, clinical trials. This has largely contributed to the rising costs of drug development.

Incremental but not dramatic change—or muddling through—may explain why pharmaceutical companies are slow to adopt truly innovative IT solutions with the potential to drive down costs, reduce cycle times and ultimately get new therapies to market faster. IT departments often look for ways to streamline current workflows rather than fundamentally disrupt them. For instance, Excel is still predominately used in clinical operations for site selection and initiation phases of starting trials, with IT managers looking to provide greater incremental value with e-rooms, email distribution groups and shared drives, without fundamentally changing the underlying workflow process.

Recently, there has been an uptick in adoption of eClinical solutions, the market for which is expanding at a compound average growth rate of 13.8%, to $6.8 billion by 2020. While these systems have driven productivity gains, they represent incremental changes, changes that do not address one of the most inefficient and costly bottlenecks of clinical trial conduct that arguably has the biggest impact on overall study timeline—study startup (SSU). SSU is an array of activities performed at the launch of a clinical trial. This early stage of development includes traditional tasks such as site identification, feasibility assessment, selection and initiation, and requires regulatory document submission, contract and budget negotiations and enrolling the first patient. It is a complex, costly process that necessitates constant coordination across multiple stakeholders, including external partners. Streamlining this process has great potential to save time and cut costs, up to 25-30%, according to some estimates. Disrupting this process and reducing cycle times is not an incremental change. Perhaps that is why it is so difficult and fraught with resistance by stakeholders and organizations alike.

With signs that the CRO market is maturing (by 2020, it is estimated that 72% of trials will be outsourced), SSU is becoming a competitive differentiator providing clear operational improvements and sponsors with real-time metrics into the early stages of starting clinical trials—at a time when sponsor oversight and business intelligence initiatives are paramount. This offers real, disruptive change.

Increased competition in the CRO market and pressure from pharmaceutical shareholders to rein in costs and improve financial performance are likely to force the hand of those waiting on the sidelines to streamline SSU. Until then, early innovation adopters are gaining a foothold against their competitors by leveraging SSU optimization technology to drive down costs and reduce cycle times.

In the meantime, how can we facilitate the change from muddling through to rational decision-making, a change which will drive the adoption of innovative technology

Challenges with Excel

1. Lack of project management capabilities
2. Lack of regulatory compliance
3. Unsecured data
4. Manual entry is error-prone
5. Lack of version control or centralization
6. Inefficient workflows
7. Collaboration and communication among stakeholders
8. Oversight and partner selection
9. Decentralization
10. Real-time reporting

by pharma? While there may be no silver bullet, there is a silver lining. By continuing to drive industry awareness, supporting change agents and promoting the success of those early adopters, we can reset the expectations of all organizations involved in undertaking trials—empowering a learning process for incumbent or new clinical executives with such experience and knowledge, or those with just an innate willingness to change things for the better. *Anything less will be unacceptable*.

Today's leading organizations outrace their competition by outlearning them. 

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