



Innovation Detractors in Pharma

Simply “doing the same thing better” is not enough.

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Innovation is a critical ingredient for companies striving to sustain an advantage in the increasingly competitive global marketplace. Simply “doing the same thing better” is not enough. Across multiple industries, companies are focusing their top teams on leveraging social, mobile, analytics, and cloud to implement “disruptive” technologies designed to promote innovation and transform the enterprise. And while many industries are blazing new trails in pursuit of new technologies, pharma appears to be lagging behind, often adopting a watch and wait approach. In most industries, the pace of technology change has increased so much that corporate IT leaders who don’t embrace emerging trends end up behind the competition and eventually out of business. Can we really say the same is true for pharma companies?

The modern innovator’s dilemma

Technology adoption – particularly in highly controlled regulated environments – is a complex issue that deserves careful thought and consideration before making any sweeping changes. Long cycle times, an elaborate regulatory environment, and just plain complicated science are obvious challenges and innovation detractors (sowing the seeds of FUD: Fear, Uncertainty, and Doubt) most certainly contribute to the technology risk aversion we see in pharma today. Despite these challenges, life science organizations adopt new technologies all the time; high-throughput screening, continuous manufacturing, targeted therapies, etc. So what’s the problem? Most life science companies will 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 (e.g., clinical trials). Why are point solutions readily adopted as opposed to technologies that can drive efficiencies from an end-to-end perspective, offering truly transformational paradigm shifts?

Maybe not all innovation is the same. This is what Clayton Christensen argues in his age-old but still renowned work, “The Innovator’s Dilemma.” Christensen argues that the innovator’s dilemma is that “doing the right thing is the wrong thing.” Very often, real innovation doesn’t occur because executives made bad decisions but because they made **good** decisions, the same kind of good decisions that had made those companies successful for decades. As Christensen saw it, it wasn’t so much a problem as a missed opportunity, like a plane that takes off without you, except that you didn’t even know that planes existed in the first place.

Christensen said that so-called “sustaining innovations,” designed to keep the lights on, may result in critical oversights, such as missing what an entirely untapped customer wanted.

Could it be that the modern innovator’s dilemma in pharma looks different but bears similar markings? Seemingly good decisions are made about investing in new IT platforms that result in “sustaining innovations” but missed opportunities, perhaps rooted in a misunderstanding of the potential advantages of technology, risk aversion, or perhaps just a simple fear of change. Wearables and mobile (so-called “mHealth technologies”) are timely examples that hold the potential to disrupt data collection processes, ease the burden on patients, speed patient recruitment, and generally reduce sponsor burden in clinical trials. But adoption requires major upfront changes in software, IT integration, and data collection practices. A recent survey conducted jointly by SCORR Marketing and Applied Clinical Trials on the use of mHealth reveals that there continues to be slow adoption of these technologies, despite the perceived benefits. When asked if the positives of wearables outweigh the negatives, 95 percent of respondents said yes, but only 31 percent of respondents reported having used a wearable drug delivery device in a clinical trial in the past year. When asked which group was the most resistant to adoption, 38 percent pointed to pharma companies, with only 22 percent citing clinical sites and 15 percent citing patients

The science of muddling through

Another way to look at the issue is to consider how large, complex organizations make decisions. The idealized view envisions highly organized and thorough organizations that systematically evaluate a wide range of alternatives and then choose the best of these choices based on careful analysis. But a more realistic analysis suggests that organizations often make decisions based on a much more limited range of information and analysis. In one of the earliest formulations of this view (from Charles Lindblom’s classic article “The Science of Muddling Through” in 1959), bureaucratic organizations make decisions by “muddling through.” Lindblom took issue with the so-called “rational-comprehensive” approach, which begins by addressing a particular problem issue by ranking objectives, followed by the identification and comprehensive analysis of all alternative solutions, making sure to account for all potential factors. Lindblom argued that instead of comprehensive analysis of every option, a much more constrained process of “successive limited comparison” is really how solutions are developed. According to this “branch” method, stakeholders usually look only at solutions that differ in relatively small degree from the solutions currently in effect, thereby reducing the number of alternatives to be investigated while simultaneously narrowing the scope of investigation. In other words, they look at two nearby branches, *not the whole tree, roots and all*.

Driving incremental but not dramatic change – or muddling through – may explain why organizations, especially large, complex pharmaceutical 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 market faster. Relying on the ‘branch method’ of “successive limited comparison”, IT departments look for ways to streamline current workflows rather than fundamentally disrupt them. For instance, Excel is still predominately used for site selection and initiation phases of starting clinical trials, with IT managers looking to provide greater incremental value with e-rooms, email distribution groups, shared drives, etc., without fundamentally changing the underlying workflow process.

Recently, there has been an uptick in adoption of cloud-based solutions such as clinical trial management systems (CTMS), electronic data capture (EDC), and the electronic trial master file (eTMF) – software, which automates existing paper-based systems. And 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 – 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 selection and initiation, regulatory document submission, contract and budget negotiations, and enrolling the first patient. It is a complex, costly process that requires constant coordination across multiple stakeholders, including external partners. Streamlining this process has great potential to save time and cut costs, up to 25-30 percent 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.

In the meantime, how can we facilitate the change from muddling-through to rational decision-making? While there may be no silver bullet, there is a silver lining – by driving industry awareness, supporting change agents, promoting the success of those organizations striving for real-change and realizing the benefits, early adopters will achieve efficiencies and reset expectations for everyone else. This will spur a learning process either by managers in the firm or through the arrival of new managers with such experience and knowledge, or those with just an innate willingness to change things for the better. As Gandhi said, “Be the change you wish to see in the world.”



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