

Introduction

The role of information capital in the value chain of the pharmaceutical industry is to gain competitive advantage, primarily through differentiators that occur in the areas of research and development, and during the conduct of clinical trials. The fields of medical research are sometimes advancing faster than the implementation of the transactional and decision support systems needed to collate the data, coordinate the activities, and provide management information in such a timely fashion as to empirically support decisions toward obtaining product approval by government regulators.

This paper will present information that demonstrates how the pharmaceutical industry has been too slow in adopting information technology resources toward achieving strategic goals.

The Problems

Today's market offers robust software for electronic data capture (EDC) and data mining, Internet-based portals for communication among clinical partners and regulators; and industry-accepted standards for data transmission and submission, yet, according to the Centre for Medicines Research International (CMR, 2004), a lack of adoption of these technologies has contributed to an increase in the median time between critical clinical trial milestones.

In 2004, Merck Capital Ventures (MCV), in conjunction with Science Applications International Corporation (SAIC), embarked on a study of key factors influencing IT adoption rates. The study sought to identify both technical and organization challenges that stall IT acceptance in the pharmaceutical industry. What emerged is a picture of today's IT status from the perspective of seven strategic job

families that should be targeted for technology improvements, including those in the areas of:

Protocol Design and Study Start Up

Patient and Investigator Recruitment

Clinical Trial Management

Clinical Data Management

Data Analysis

Clinical Supplies

Regulatory and Safety

The MVC/SAID study (2004) revealed, in part, a stubborn adherence to paper-based systems in the face of expansive, searchable, cost-effective solutions, but also a growing acceptance of IT powered by regulatory pressures to improve the efficiency of submissions and adverse event reporting. Technology has a profound ability to affect the seven core functions of the pharmaceutical industry's strategy map. Functional applications such as portals, collaboration, decision support tools and work flow management impact six of the seven core functions. Document management and project and portfolio management impact all seven. Improving each of the strategic functions is fraught with challenges related to inadequate or an absence of technology, or the mixed use of electronic and paper-based methodologies.

The present state of clinical development remains largely a paper-driven process that is cumbersome, time consuming, and costly, contends the U.S. Department of Health and Human Services (2004), stating that geographically dispersed stakeholders performing internal protocol review via paper copies delay study startup. Paper-based

monitoring and reporting of adverse events slow response time. Response time and quality suffer, and data are not visible to the sponsor in real or near real time. Important metadata cannot be easily generated, and there is no simple way to search data to highlight problematic investigative sites or facilitate decision making early enough to make a difference. And whether trial data are stored electronically or with paper, they tend to be stored in disparate, incompatible systems and formats that complicate data entry, data exchange among stakeholders, query resolution, and data reconciliation during the trial and before database lock.

Several sources report that clinical trial durations and costs have not been improving across the industry. Thomson CenterWatch and Pharmaceutical Research and Manufacturers of America (2003) claim increased spending on clinical development. As well, the Food and Drug Administration (2004) presented its current views on deteriorating drug development performance reporting a 55 percent increase has occurred since 2000 in investment required to launch a new drug, and if biomedical science is to deliver results, there must be a focused effort on improving the medical product development process through the implementation of technology and process upgrades.

Another of the seven core functions, clinical data management, involves collecting information from numerous sources such as investigative sites and laboratories. Often, those data are collected in both electronic and paper format, in the absence of collection standards, resulting in multiple trial-specific databases, an array of related systems, and extended time for data reconciliation. As reported in a 2002 issue of the Drug Information Journal (Palm, 2002), these systems, sometimes numbering into the hundreds

within a single company, have become ingrained as legacy solutions and loom as huge barriers for change.

Document management solutions present a major challenge for pharmaceutical companies to handle the staggering amount of data generated throughout a trial contained in documents in multiple formats—paper, electronic, and digital—and sometimes requiring updating, or versioning, during the trial.

Another strategic job family, regulatory and safety, attempts the difficult task of integrating data from various functional areas throughout the trial process. Information from distinct databases/systems created for regulatory purposes tend not to be aggregated, limiting data mining capability and ability to respond to regulatory questions or investigate adverse events in a timely manner.

Traditional document management applications are not designed to handle these new formats and their features. A robust document management system that provides a common repository with searchable attributes, electronic routing and approval, and life cycle management capabilities such as authoring, version control, and archiving are fundamental enabling technologies.

Data mining, data warehousing, and enterprise application integration functions are also key to reposing and provisioning data to users. Integration and aggregation of e-solutions allow sponsors to search and query data across all studies involving a specific product. Similarly, they allow regulatory agencies to search advanced databases and a broad range of data types to identify similar patterns in other drugs with the same chemical structure. This search capability, using visualization tools and adoption of centralized data, metadata, and vocabulary standards, is critical for early detection of

potential safety issues and represents a major advance over non-searchable systems in which signals are possibly masked in data stored in multiple formats and locations and coded using different vocabularies.

Organizational Considerations

Implementing technologies that yield an expected high return on investment requires changes in business processes. These processes are the convergence of tools and resources and revised work practices. They are strongly influenced by regulatory guidelines that are creating specific requirements to which technologies and processes must conform. To implement the requisite IT solutions successfully within an organization, process change is also elemental. Without it, it is unlikely that new technology meant to improve core function operations will yield expected, significant long-term benefits. In fact, as suggested by Kush and Maloy (2003), some pharmaceutical companies who are achieving short term benefits from new technologies without having changed existing processes now realize they have further entrenched suboptimal business practices, finding it even more difficult to make substantive changes. Implementing cultural changes won't be easy or cheap. Process change that is tantamount to system overhaul in the short term is hardly a realistic goal because of the enormity of the undertaking and the amount of change it would entail. People tend to resist these types of changes, as suggested by draft results of a CDISC (2004) survey in which 46% percent of sponsor respondents cited "concerns about changing current process" as a key reason for data collection technology adoption delays. With each acceptance of a new technology, however, the enterprise nudges closer to its goal of system-wide solutions leading to greater operational efficiency and quality.

This technology-acceptance model applies to any industry, but it certainly resonates with the pharmaceutical sector which has been notoriously slow to adopt electronic solutions despite evidence supporting the value of system-wide interoperable technologies. As the industry considers technology adoption, it is important that it not settle for a series of study-by-study or department-by-department solutions as this will, at best, yield minimal improvement, and at worse, add to the problem of legacy systems and create even greater costs in clinical development. Companies with cultures that recognize this are likely to reap the benefits of system-wide technology ahead of companies that lag behind.

Regulatory Considerations

More than ever, the most significant factor driving the industry's deployment of IT in clinical trials is the adoption of data-related standards by regulatory agencies. FDA, for example, launched the Data Standards Council to coordinate the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout FDA and that standards are consistent with those used outside the agency.

The industry should also expect increased adoption of Electronic Health Records in U.S. and Europe and continued government and payer pressures for cost and cycle time reductions in drug development. Both will have an impact on the use of IT because both require efficient and effective data exchange and management.

Conclusion

This paper identified three fundamental and interrelated forces that drive change in the pharmaceutical industry: technology, business processes, and regulatory guidelines.

Technological advances enable new workflows and promises of interoperability and integration of function, but technology alone has little power to create meaningful change. Successful implementation of electronic solutions requires changes in business processes and an appreciation of how difficult it is for organizations to take those first steps away from paper-based clinical systems that have worked for decades.

Ingrained behaviors are difficult to change, but the results of system-wide technology solutions are indisputable: better quality data, accelerated cycle times, and greater cost efficiencies. Also driving the move toward greater use of technology are regulatory forces that are focusing on improved collection, transmittal, and storage of data. Companies that have set a vision for the future, support a culture for change, and implement processes and projects to move forward are generating tangible rewards, creating learning organizations, and positioning themselves to be industry leaders. Novartis, for example, implemented EDC in 2001, and now uses EDC in approximately 60 percent of Phase I trials and nearly 100 percent of Phases II and III trials (M. Uhling, 2004). As a result, the company claims to have reduced the number of contractors in the data management department from 90 to 20, and cut the number of queries to four per 1,000 data points as compared to 51 per thousand for paper-based trials. Cost have been reduced to \$4.60 per page for EDC vs. \$23 per page using paper, and the median time for finalizing clinical databases dropped to four days with EDC vs. 10 weeks for paper. The company claims that the technology upgrades have resulted in annual savings exceeding \$100 million (Korieth, and Zisson, 2005).

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