Creating a Data-Driven Business in Pharmaceuticals and Life Sciences

By unifying data with modern integration technologies, pharmaceutical organizations can accelerate drug discovery research, improve trial efficiency, strengthen regulatory compliance and connect with supply chain systems.

Leading pharmaceutical and life sciences organizations that are effectively managing digital disruption have made great strides in harnessing data for insights and informed business decisions. They're gaining a competitive edge over rivals that struggle to create a cohesive view of data spread across their large enterprises and partner organizations.

Mismanaging data leads to decreased productivity and a lack of focus in research that can limit important process improvements and increase time to analysis and outcomes — which all delay the drive to real innovation. Research by the Tufts Center for the Study of Drug Development has shown that the cost of drug development is rising, with the full cost of an approved drug at an average of $2.87 billion[1].

Life sciences companies need to reduce R&D costs to better compete as healthcare providers, governments and consumers put increasing pressure on manufacturers to reduce drug prices. Since research efficiency is aided by the creation and analysis of data insights, a cohesive view and contextual awareness across all R&D activities will improve time to insight. Because of differences among stakeholders, data should be delivered in the context that matters most for each group.

Improved transparency builds trust from the public and regulators, contributing to a lower regulatory burden. Additionally, new and emerging technologies including machine learning, AI and crowdsourcing can drive better data analysis, modeling and, most importantly, prediction. Companies like the UK-based McLaren Applied Technologies, a leader in motorsports, electronics and healthcare innovation, are showing that data science can play a major role in drug discovery, patient safety and healthcare.

Pharmaceutical firms that want to systematically unleash the potential from their data need to embark on a strategic remake of their data architecture. Establishing a single data platform in which new applications and technologies can be simply plugged in will accelerate their discovery processes and bring expanded value to their investments.

However, legacy pharmaceutical and life science companies continue to struggle to bring together their data silos for their data science initiatives. Bottlenecks, including regulatory compliance, legacy infrastructure and disconnected on-premise applications, are slowing progress. Another complication is legacy interfaces that are coding-heavy and require frequent re-validation for interfaces related to GxP good practices.

[1]Outsourcing-Pharma, https://www.outsourcing-pharma.com/Article/2016/03/14/Tufts-examines-2.87bn-drug-development-cost.

To unleash the potential of their data, pharmaceutical companies need to strategically remake their data architecture.

Pharmaceuticals and Life Sciences Today

Companies are increasingly focused on bringing targeted therapies, new medicines, and new uses for existing medicines to market faster. Decreasing the timeline to develop and move a new drug to market presents significant advantages for all involved.

A critical element to accelerating drug development and delivery is increasing researcher productivity and collaboration across organizations — including subcontractors and contract research organizations (CROs). This can decrease the price per study while improving focus on those higher value and opportunistic therapeutics.

At the same time, the expanding digitization of data has significantly increased the complexity of pharmaceutical R&D and clinical trials data. Clearly, "with advances in computing power, scientists no longer go by trial and error. Rather, they test the way specific genetic variations generate particular traits and diseases."[2]

Adding to this is the need to share data between larger partner ecosystems. This change offers the potential for increased research productivity through better internal and external collaboration. This can lead to accelerated time to market and a longer patent life for a compound, drug or therapy.

The expanding digitization of data means that pharmaceutical R&D and clinical trials data has increased significantly.

To achieve this, four things are needed:

1. The ability to share documents, procedures and standard operating procedures with partners and CROs. One example is an integrated document management system connecting cloud and on-premise systems, such as Veeva Vault, OpenText Documentum and IBM FileNet.
2. The ability to integrate supply chain systems and connected devices ensuring product quality (e.g., temperature and cold room condition monitoring, inventory availability, etc.).
3. The ability to respond to new regulations, especially the Drug Supply Chain Security Act (DSCSA) from the U.S. Food and Drug Administration. Product serialization and tracking and tracing solutions require robust integration across manufacturers, wholesale distributors and pharmacies.
4. The ability to create golden records and a single source of truth for master records management, connecting third-party data providers and internal systems to ensure data consistency.

With time-to-market a critical profitability factor in drug discovery, it is important to capture and relate all data through the entire drug discovery process. From determining candidates and correlating them to their market opportunity, to identifying and recruiting clinical trial participants, pharmaceutical companies make a significant investment before they can be assured of any return.

Having access to disparate data sources from prior research can quickly narrow the list of candidates, saving valuable research resources by eliminating candidates who may fall outside requirements or are known to not comply with prescribed therapies. These changes matter because it takes years for a new medicine to reach the market, with much of the time spent in the clinical trials process.

[2]The Fourth Industrial Revolution, Klaus Schwab, 2016, page 21

In addition, productivity can be improved through a focus on patient recruitment and proactive monitoring to limit patient drop-out. At the same time, clinical trials are quickly being enabled by additional data coming from the increased use of wearables, home nursing and patient self-recruitment. For the data savvy, this opens up totally new data sets.

What Is Holding Back the Pharmaceutical Industry?

For most pharmaceutical and life sciences organizations, data and knowledge sharing is undermined by difficulties in internal collaboration and the complexity of global pharmaceutical ecosystems. This makes it challenging to share data on drug discovery and reduce costs from discovery to production.

Today, only traditional clinical test data is used in drug development, though real-world data contains many more pivotal data points such as patient health records and social data. The Internet of Things (IoT) makes it possible to bring into the clinical trial process clinical systems data and various biometric data collected from sensors. Including these data sources can significantly improve clinical trial productivity.

Data held in organizational silos not only limits productivity but can also negatively impact revenue. The industry has many instances in which a drug developed for one purpose also showed positive results in other fields of study. Capturing that data can provide new avenues for research and, ultimately, revenue. Cataloging research data is essential to enabling better collaboration and quickening the discovery of unexpected efficacies for drugs.

In addition, pharmaceutical companies face an increasing need to make use of supplier quality data in production. Capturing and recording batch control data, production sites and environmental data such as temperature and humidity can introduce new degrees of quality control throughout the entire drug lifecycle.

At Dell Boomi, we frequently hear from our pharmaceutical customers that they are struggling with the following issues:

- Reducing the timeline for drug discovery and evaluation
- Improving clinical trial productivity
- Managing pressures of regulatory compliance
- Creating a scalable, compliant and integrated architecture
- Speeding the rollout for initiatives aimed at improving patient care
- Establishing data governance across a heterogeneous data fabric

Solving these issues across multiple domains requires two things. First is the ability to isolate the problems versus just identifying symptoms. Second, data needs to be contextualized and corrected before it is analyzed or used.

Dell Boomi for Pharmaceutical and Life Science Companies

Boomi's unified platform provides pharmaceutical organizations with a unique opportunity to accelerate drug discovery research, improve trial efficiency, strengthen regulatory compliance and connect with supply chain systems to ensure traceability and avoid counterfeit drugs.

Boomi is the data integration standard at 14 of the top 15 pharmaceutical companies, delivering bottom line impact in R&D cost-efficiency and overall business agility. For example, one Boomi customer has dramatically increased scientists' efficiency by rapidly distributing experimental results and reducing unnecessary experimental duplication. Another customer credits data management in its ability to reduce clinical trial duration, with savings of up to $1 million per day.

Boomi helps companies integrate high-quality, contextualized pharmaceutical production, transaction and interaction data in a multipurpose platform. The platform ensures affordable, enterprise-scale data availability across all processes.

The Boomi platform equips the pharmaceuticals and life sciences industry to become more data-centric for better business decisions. A Boomi-based holistic approach to data management enables pharmaceutical companies to:

- Capture data from any internal or external on-premise or cloud system, including machine data streaming and real-time or batch-oriented transactional data
- Deploy complex event processing to respond to data on acquisition and enable both real-time and predictive business process models
- Quickly operationalize new data sources for clinical trials, including social media and data from external sources (e.g. wearables and patient self-enrollment)
- Quickly roll out changes with Boomi's low-code configurable environment and business process capabilities
- Support GxP interfaces and share GxP data with Boomi as the primary integration platform

For more than a decade, Boomi has been helping companies move beyond one-off data integration projects. With our unified platform, we help our customers establish data integration and management as a core competency. In the pharmaceutical industry, we provide leading companies with capabilities for fast, flexible data and application integration, master data consistency, API management, workflow automation and electronic data interchange.

Those industry-leading capabilities empower companies to fulfill top business objectives:

- **Revolutionize business processes.** A data-centric approach drives greater pharmaceutical R&D efficiency and supports improved supply chain transparency and improved patient security.
- **Create data-driven drug discovery and evaluation.** Data is at the center of driving this transformation. With better, more available data, pharmaceutical companies can more rapidly discover, integrate and consolidate data to generate new insights.
- **Improve clinical trial productivity** through a focus on site and patient recruitment, proactively monitoring to limit patient drop-out.
- **Integrate internal and external pharmaceutical supply chain systems** to ensure traceability and avoid counterfeit drugs.

By making an intelligent data platform central to operations, pharmaceutical and life sciences companies will be well-positioned to achieve the new levels of agility, cost-efficiency and collaborative innovation needed to excel in a rapidly changing healthcare environment.

Learn more about how Boomi can help you build your CEM capabilities
boomi.com/integrate

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