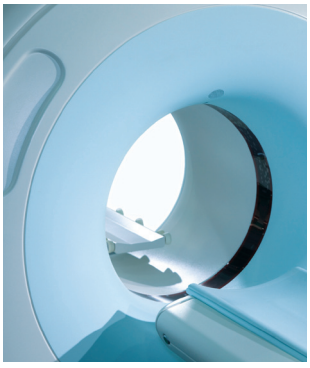
McKinsey&Company

McKinsey Center for Government

How Big Data Can Revolutionize Pharmaceutical R&D



Jamie Cattell, Sastry Chilikuri, Michael Levy

How Big Data Can Revolutionize Pharmaceutical R&D

Pharmaceutical R&D suffers from declining success rates and a stagnant pipeline. Big data and the analytics that go with it could be key elements of the cure.

After transforming customer-facing functions such as sales and marketing, big data technologies are extending their reach to other parts of the enterprise. In R&D, for example, big data and analytics are being adopted across industries, including pharmaceuticals.

The McKinsey Global Institute estimates that applying big-data strategies to better inform decision making could generate up to $100 billion in value annually across the US health-care system, by optimizing innovation, improving the efficiency of research and clinical trials, and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches.[1]

1 Our work builds on insights from several reports and articles, all available at mckinsey.com: James Manyika et al., "Big Data: The Next Frontier for Innovation, Competition, and Productivity," McKinsey Global Institute, May 2011; Peter Groves et al., "The Big-Data Revolution in Health Care: Accelerating Value and Innovation," January 2013; and Ajay Dhankhar et al., "Escaping the Sword of Damocles: Toward a New Future for Pharmaceutical R&D," *McKinsey Perspectives on Drug and Device R&D*, 2012.

The big-data opportunity is especially compelling in complex business environments experiencing an explosion in the types and volumes of available data. In the health care and pharmaceutical industries, data growth is generated from several sources, including the R&D process itself, retailers, patients, and caregivers. Utilizing these data will improve the ability of pharmaceutical companies to identify new potential drug candidates and develop them into effective, approved, and reimbursed medicines more quickly.

Imagine a future in which the following scenarios are possible:

- Predictive modeling of biological processes and drugs becomes significantly more sophisticated and widespread. By leveraging the diversity of available molecular and clinical data, predictive modeling could help identify new potential-candidate molecules with a high probability of being developed into drugs that act on biological targets safely and effectively.

Tremendous value could be unlocked by applying big-data techniques to pharmaceutical R&D. Eight technology-enabled measures—including portfolio decision-making support and the use of smart devices—should expand data collection and improve data management and analysis. Companies that can overcome challenges related to organization, analytics, and mind-sets could see a much-needed boost in R&D innovation and efficiency.

- Patients are identified for enrollment in clinical trials on the basis of more sources—for example, social media—than doctors' visits. Furthermore, to target specific populations, the criteria for including patients in a trial could consider significantly more factors (for instance, genetic information), thereby enabling smaller, shorter, less expensive, and more powerful trials.

- To avoid significant and potentially costly issues such as adverse events and unnecessary delays, trials are monitored in real time to rapidly identify safety or operational signals requiring action.[2]

- Instead of rigid data silos, which are difficult to exploit, data are captured electronically and flow easily between functions—for example, discovery and clinical development—as well as to external partners such as physicians and contract research organizations (CROs). This easy flow is essential for powering the real-time and predictive analytics that generate business value.

That's the vision. However, many pharmaceutical companies are wary about investing significantly in improving big-data analytical capabilities, partly because there are few examples of peers creating a lot of value from it. However, we believe that investment and value creation will grow and that pharmaceutical companies would do well to get over their hesitation. The road ahead is indeed challenging, but the big-data opportunity in pharmaceutical R&D is real, and the rewards will be great for companies that succeed.

The big-data prescription for pharmaceutical R&D

Our research suggests that by implementing eight technology-enabled measures, pharmaceutical companies can expand the data they collect and improve their approach to managing and analyzing these data.

Integrate All Data

Having access to consistent, reliable, and well-linked data is one of the biggest challenges facing pharmaceutical R&D. The ability to manage and integrate data generated at all stages of the value chain—from discovery to real-world use following regulatory approval—is a fundamental requirement for companies that aim to derive maximum benefit from technology trends. Data are the foundation upon which value-adding analytics are built. Effective end-to-end data integration establishes an authoritative source for all pieces of information and accurately links disparate data regardless of the source—be it internal or external, proprietary or publicly available. Data integration also enables comprehensive searches for data subsets based on the linkages established rather than on the information itself. Smart algorithms that link laboratory and clinical data, for example, could automatically create reports that identify

2 The term "adverse events" means harm to or death of trial participants.

related applications or compounds and raise red flags concerning safety or efficacy.

The implementation of end-to-end data integration requires a number of capabilities, including trustworthy data and document sources, the ability to establish cross-linkages between elements, robust quality assurance, workflow management, and role-based access to ensure that specific data elements are visible only to those who are authorized to see them. Pharmaceutical companies generally avoid overhauling their entire data-integration system all at once because of the logistical challenges and costs involved. However, at least one global pharmaceutical enterprise has employed a "big bang" approach to remaking its clinical IT systems.

Companies typically employ a two-step approach: First, they prioritize the specific data types (usually clinical data) to address and create additional data-warehousing capabilities as needed. The goal is to tackle the most important data initially, in order to obtain benefits as soon as possible. This step alone can take more than a year and requires significant infrastructure and procedural changes. Second, the company develops an approach for the next levels of priority data, including scenario analysis, ownership, and expected costs and timelines.

Collaborate Internally and Externally

Pharmaceutical R&D has been a secretive activity conducted within the confines of the R&D department, allowing little internal and external collaboration. By breaking the silos that separate internal functions and enhancing collaboration with external partners, pharmaceutical companies can extend their knowledge and data networks. Whereas end-to-end integration aims to improve the linking of data elements, the goal of collaboration is to enhance the linkages among all stakeholders in drug research, development, commercialization, and delivery.

Maximizing internal collaboration requires improved linkages among the different functions, such as discovery, clinical development, and medical affairs. This can lead to insights across the portfolio, including clinical identification and research follow-up on potential opportunities in translational medicine or identification of personalized-medicine opportunities through the combination of biomarkers research and clinical outcomes.[3] Predictive sciences can also recommend options at the research stage on the basis of clinical data or simulations.

External collaborations are those beyond the company's four walls that involve the company and

3 The term "translational medicine" refers to the process of turning new scientific discoveries into effective health improvements and medicines.

stakeholders, including academic researchers, CROs, providers, and payers. The following examples show how effective external collaboration can broaden capabilities and insights:

- External partners such as CROs can quickly add or scale up internal capabilities and provide access to expertise in, for example, best-in-class management of clinical studies.

- Academic collaborators can share insights from the most recent scientific breakthroughs and make a wealth of external innovation available. Examples include Eli Lilly's Phenotypic Drug Discovery Initiative, which enables an external researcher to submit a compound for screening using Lilly's proprietary tools and data to determine whether it is a potential drug candidate. Participation in the screening does not require the researcher to give up intellectual property, but it does offer Lilly a first look at new compounds, as well as an avenue for reaching researchers who are not typical drug-discovery scientists.

- Collaborative "open space" initiatives enable experts to address specific questions or share insights. For example, the X PRIZE Foundation provides financial incentives for teams that successfully meet a big challenge (such as enabling low-cost manned space flight). InnoCentive, another example, offers financial incentives to individuals or teams that address a specific problem (such as determining a compound's synthesis pathway).

- Customer insights can be used to shape strategy throughout the pipeline progression.

Some pharmaceutical companies have made inroads in improving internal and external collaboration. This involves addressing a number of challenges that include establishing communications systems and governance that enable appropriate and effective information exchange. Another challenge is to promote a shift in mind-set, moving away from a commitment to withhold all data toward a willingness to identify data that can be shared and with whom the data can be shared. In addition, pharmaceutical enterprises must understand and mitigate the legal, regulatory, and intellectual-property risks associated with a more collaborative approach.

Some pharmaceutical companies start to improve collaboration by identifying data elements they are willing to share with specific sets of trusted partners—such as CROs—and establishing privileged and near-real-time access to data produced by external partners. Such steps are only the beginning, however: they are essentially just a way to expand the "circle of trust" to select partners.

Employ IT-Enabled Portfolio Decision-Making Support

To ensure the appropriate allocation of scarce R&D funds, it is critical to enable expedited decision making for portfolio and pipeline progression. Pharmaceutical companies often find it challenging to make appropriate decisions about which assets to pursue or, sometimes more important, which assets to kill. Previously made personnel or financial investments can influence decisions at the expense of merit, and many companies lack appropriate decision-making support tools for making tough calls.

IT-enabled portfolio management allows for making data-driven decisions quickly and seamlessly. Whenever possible, smart visual dashboards allow rapid and effective decision making, including decisions regarding the analysis of current projects, business development opportunities, forecasting, and competitive information. Such visual systems can provide high-level dashboards that permit users to make deep examinations of the data. Ideally, these systems include information that bolsters managerial decision making as well as detailed tactical information, and they should

make asset performance and opportunities more transparent.

In addition to meeting the technical requirements, best practice portfolio decision making follows a process with defined timing, deliverables, service levels, and stakeholders. Anyone involved in the process is given clear roles and authority (for example, each person's ability to make decisions should be defined). Resource allocation is determined on the basis of a systematic approach that accommodates top-down budgetary requirements and bottom-up requests. And innovation boards at the corporate level and at the business unit or therapeutic-area level should review the portfolio regularly. The boards assess, manage, and prioritize the portfolio on the basis of the corporate strategy and changes in the business landscape or industry context.

Leverage New Discovery Technologies

Pharmaceutical R&D must continue to use cutting-edge tools. These include sophisticated modeling techniques such as systems biology and high-throughput data-production technologies—that is, technologies that produce a lot of data quickly. For example, next-generation sequencing will, within approximately 24 months, make it possible to sequence an entire human genome at a cost of roughly $100.

The wealth of new data and improved analytical techniques will enhance future innovation and feed the drug development pipeline.

Integrating vast amounts of new data will test a pharmaceutical company's analytical capabilities. For example, a company will need to connect patient genotypes to clinical-trial results to pinpoint opportunities for improving the identification of responsive patients.

Such developments could make personalized medicine and diagnostics an integral part of the drug development process rather than an afterthought and could lead to new discovery technologies and analytical techniques.

Deploy Sensors and Devices

Advances in instrumentation through miniaturized biosensors and the evolution of smartphones and their apps are resulting in health measurement devices that are increasingly sophisticated. Pharmaceutical companies can deploy smart devices to gather large quantities of real-world data not previously available to scientists. Remote monitoring of patients using sensors and devices represents an immense opportunity. Such data could be used to facilitate R&D, analyze drug efficacy, enhance future drug sales, and create new economic models that combine the provision of drugs and services.

Remote-monitoring devices can also add value by helping patients adhere to their prescriptions. Examples of devices that are under development include smart pills that can release drugs and relay patient data, as well as smart bottles that help track usage. Technology and mobile providers are offering services such as data feeds, tracking, and analysis to complement the benefits of medical devices. The devices and services, combined with in-home visits, have the potential to reduce health care costs through shortened hospital stays and earlier identification of health concerns.

Raise Clinical-Trial Efficiency

A combination of new, smarter devices and fluid data exchange will enable improvements in clinical-trial design and outcomes as well as greater efficiency. Clinical trials will be increasingly adaptable, able to react to drug safety signals seen only in small but identifiable subpopulations of patients. Examples of potential clinical-trial efficiency gains include the following:

- Dynamic sample-size estimation (or reestimation) and other protocol changes

could enable rapid responses to emerging insights from clinical data. Efficiency gains are achieved by enabling smaller trials for equivalent power or shortening the time necessary to expand a trial.

- Responding to site differences in patient recruitment rates would allow a pharmaceutical company to address lagging sites, bring new sites online if necessary, and increase recruiting from more successful sites.

- Increased use of electronic-data capture could help in recording patient information in the provider's electronic medical records. Using electronic medical records as the primary source for clinical-trial data rather than a separate system could accelerate trials and reduce the likelihood of data errors and duplication that result from manual data entry.

- Next-generation remote site monitoring enabled by fluid, real-time data access could improve management and response to problems that arise in trials.

Improve Safety and Risk Management

Safety is a competitive advantage in regulatory submissions and following regulatory approval, once the drug is on the market. Safety monitoring is moving beyond traditional approaches to sophisticated methods that allow for the identification of possible safety problems arising from rare adverse events. Furthermore, problems could be detected from a range of sources, for example, patient inquiries on websites and search engines.

Online physician communities, electronic health records, and consumer-generated media are also potential sources of early signals regarding safety issues and can provide data on the reach and reputation of different medicines. Bayesian analytical methods, which can identify adverse events from incoming data, could highlight rare or ambiguous safety signals with greater accuracy and speed.

An early response to physician and patient sentiments could prevent regulatory and public-relations backlashes. The US Food and Drug Administration is investing in the evaluation of electronic health records through the Sentinel Initiative, a legally mandated electronic-surveillance system that links and analyzes health care data from multiple sources. For this system, the FDA has secured access to data on more than 120 million patients nationwide.

Sharpen Focus on Real-World Evidence

Real-world outcomes are gaining importance with pharmaceutical companies as payers increasingly impose value-based pricing. Pharmaceutical companies can respond to this cost-benefit pressure by pursuing drugs for which they can show differentiation through real-world outcomes, such as therapies targeted at specific patient populations. In addition, the FDA and other government organizations have created incentives for research on health economics and outcomes.

To expand their data coverage beyond clinical trials, some leading pharmaceutical companies are creating proprietary data networks to gather, analyze, share, and respond to real-world outcomes and claims data. Partnerships with payers, providers, and other institutions are critical to these efforts.

The challenges of a big-data transformation

For a big-data transformation in pharmaceutical R&D to succeed, executives must overcome challenges associated with organization, technology and analytics, and mind-sets.

Organization

Organizational silos result in data silos. Functions typically have responsibility for their systems and the data they contain. A data-centric view, with a clear owner for each data type across functional silos and through the data life cycle, can greatly facilitate the ability to use and share data. The expertise the data owner gains will be invaluable when developing ways to use existing information or to integrate internal and external data. Furthermore, having a single owner can enhance accountability for data quality. Such organizational changes are possible only if a company's leadership understands the potential long-term value that can be unlocked through better use of internal and external data.

Technology and Analytics

Pharmaceutical companies are saddled with legacy systems containing heterogeneous and disparate data. Increasing the ability to share data requires rationalizing and connecting these systems. There's also a shortage of people capable of developing the technology and analytics needed to extract maximum value from the existing data.

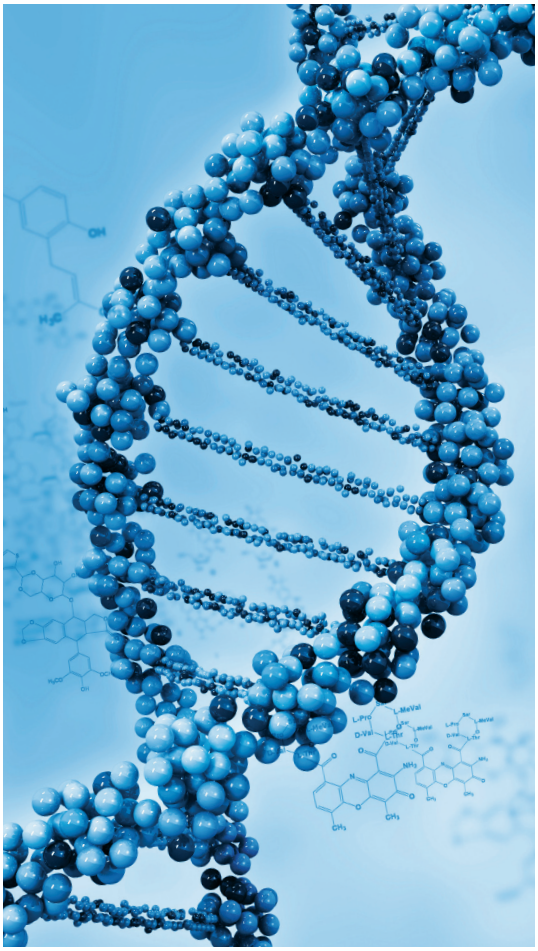
Mind-sets

The executive management of many pharmaceutical companies believe that unless they identify an ideal future state, they can gain little value from investing in the improvement of big-data analytical capabilities. Indeed, as there are few examples of pharmaceutical companies creating a lot of value from the improved use of big data, some companies seem to fear being the first mover. Compounding their hesitation is the concern that if they pursue a big-data change program, they will be subject to more interactions with regulators. Pharmaceutical companies can learn from smaller, more entrepreneurial enterprises that see value in the incremental improvements that might emerge from small-scale pilots. The experience so obtained could yield long-term benefits and accelerate the path to the future state.

■ ■ ■

Pharmaceutical companies desperately need to bolster R&D innovation and efficiency. By implementing eight technology-enabled ways to benefit from big data, companies could gradually turn the tide of declining success rates and stagnant pipelines.

Editor's note: This article was previously published in McKinsey on Business Technology.



McKinsey Center for Government
October 2013
Layout by US Design Center

www.mckinsey.com/mcg