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Digital in R&D: The \$100 billion opportunity

Insights into Pharmaceuticals and Medical Products

Sastry Chilukuri Edd Fleming Ann Westra

Digital in R&D: The \$100 billion opportunity

Digital promises to transform R&D productivity over the next decade. What will it take to realize this potential?

Healthcare today faces extraordinary challenges as aging populations, an increasing chronic diseases burden, and growth in the middle class in Asia transform patient needs. These stresses are placing new demands on innovation as health systems world-wide increase their scrutiny on value to address rising costs. Simultaneously, we are witnessing an unprecedented explosion of breakthroughs in science and technology that are redefining society and the practice of medicine.

All these changes have profound implications for biopharmaceutical research and development. Today's clinical environment is evolving rapidly and presents specific challenges: for example, the rise of personalized medicine and artificial intelligence has led to increasingly complex protocols and new end points; trials are more frequently targeted at smaller and harder-to-find patient populations; and competition has increased across the board, making the battle for trial sites and patients even more fierce. Biopharmaceutical company R&D is a series of high-risk,

high-investment decisions and the industry is facing a considerable productivity challenge in terms of identifying, testing, and bringing new drugs to market, especially in the context of the highly innovative therapies we seek today.

The R&D productivity challenge

With the average pre-tax cost of each new prescription drug estimated at almost \$2.6 billion¹ (including failures and capital costs) the spotlight is firmly on R&D productivity. The issue, long recognized, is that R&D expenditures have been increasing while drug approvals have largely been in decline for almost 50 years.

Digging further into this R&D productivity challenge in



the biopharmaceutical industry, McKinsey analysis of the ratio of revenue to R&D spend shows that productivity reached its nadir between 2008–11—with return on investment (ROI) plunging to 0.5 in 2008—following a decade-long decline (Exhibit 1).² When we first analyzed this trend two years ago, the high failure rates for investigational compounds was the single largest driver behind the

¹ Tufts Center for the Study of Drug Development, "Briefing: Cost of Developing a New Drug," November 18, 2014, http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.

² The vintage index is defined as the ratio of the first seven years of revenue for all innovative launches in a given year to the corresponding portion of R&D investment over the previous seven years.

rocketing costs of launching a single successful drug.³ Additionally, the blockbuster potential of new market entrants has often been exaggerated: an analysis found that 43 percent of consensus forecasts overestimated actual revenues by more than 40 percent.⁴

Exhibit 1

ROI vintage index over time

Productivity is improving but there is uncertainty going forward

ROI vintage index = 7 years of revenues from NME launches^{1,3} in a given year divided by the



 NME-grade products, excluding generics, biosimilars, and NDA products (ie, new derivatives, reformulations, etc); launch year based on the global market entry and first reported/expected revenues; 3-year rolling average.
Assigned based on average R&D progression and proportion of spend attributed to different R&D stages.
Inflation-adjusted to 2017 US\$; revenue values beyond 2016 are based on analyst forecasts.
Source: EvaluatePharma® May 2017; PhRMA 2016; McKinsey analysis

Encouragingly, however, the biopharmaceutical industry has found some recent reasons for optimism. Lately there has been a promising upturn in approvals and successful therapeutic launches, with productivity reaching a ROI vintage index of 1.3 in 2014. While the industry has not returned to the heady days of 1996–97, the ROI vintage index spiked at 3.1 in 1997. The signs of recovery in R&D productivity appear to be building some momentum. Developments in select

³ Kate Smietana, et al. "Improving R&D productivity, "Nature Reviews Drug Discovery, June 12, 2015, pp 455–456, https://www.ncbi. nlm.nih.gov/pubmed/26065405. Kate Smietana, et al. "Trends in clinical success rates," Nature Reviews Drug Discovery, May 20, 2016, https://www.ncbi.nlm.nih.gov/pubmed/27199245.

⁴ Myoung Cha, et al. "Pharmaceutical forecasting: throwing darts?" *Nature Reviews Drug Discovery*, October 12, 2016, https://www. ncbi.nlm.nih.gov/pubmed/?term=sarraf+p%5Bau%5D+darts.

therapeutic areas including oncology and the advent of technologies such as CRISPR⁵ are opening up a new era of precision and personalized medicine—some of which is reflected in the rise in biotech valuations that we have witnessed recently. Yet, despite these silver linings, the cost of developing new drugs continues to be a cloud over the industry and the long-term R&D productivity challenge remains to be fixed.

So what lies behind this systemic decline in productivity and how is the transition to new science affecting R&D? In part, the industry's productivity problems stem from this very transition. While looking extremely promising for the longer term, realizing the possibilities of the genomic revolution has required considerable upfront investment to translate leads and potential into medicines that can



benefit the patient. Moreover, the technology has generated an explosion of information, which has presented a new set of challenges for organizations—the equivalent of finding the proverbial needle in the haystack. Simultaneously, the hurdles relating to the regulatory requirements for demonstration of efficacy have also risen. Thus, balancing the risk-reward equation is becoming an increasingly significant factor for pharma: the failure costs of new molecular entities are climbing, which in turn are dramatically raising the overall cost of each NME.

The digital opportunity

Today we're witnessing the simultaneous maturing of numerous breakthrough technologies — genomics, nanotechnology, sensors and the Internet of Things, big data and advanced analytics, artificial intelligence (AI) and robotics, and 3D printing among others — that is unprecedented in human history. Broadly defined, digital is the application of these breakthrough technologies to radically reshape companies, industries and indeed broader society. This includes:

- Creating extreme winners and losers by industry
- Radically reshaping consumer to company interactions
- Transferring value to the consumer
- Dramatically lowering the cost base driven by technology/labor trade-offs across "processes"
- Dislocating the "role of the worker"

5 CRISPR: Clustered regularly interspaced short palindromic repeats.

For businesses, it is paramount to reinvent the core and reimagine entire business models: products and services, research and development, sales and marketing, and channels. Within biopharmaceutical R&D, digital presents the opportunity to ensure better outcomes for patients via targeted therapies; significantly reduce the cost of drug development; and accelerate cycle times to get treatments to patients faster.

In 2013 we predicted that digital technology breakthroughs would transform biopharmaceutical R&D and the wider healthcare landscape.⁶ At the time we anticipated a future where the following would not only be possible, but necessary.

- Predictive modeling of biological processes and drugs would become widespread as a result of R&D organizations using more diverse sets of molecular and clinical data. This would have a profound effect on the ability of manufacturers to identify molecules with the highest probability of successful development and to identify failures earlier.
- Patients would be matched to clinical trials using diverse data sources. They would be enrolled based upon factors such as genetic information—rather than via serendipitous visits to doctors' engaged in trials while the trials themselves would be smaller, shorter, less expensive, and generate better insights.
- Trials would be monitored "live" including using a diverse ecosystem of sensors and wearables around the patient to rapidly identify safety or operational signals requiring action, thus reducing costly delays.
- Data would flow freely among functions within pharmaceutical companies as well as to partners such as academia and contract research organizations, substantially speeding analysis and value generation.

The only surprise for us today is just how much change there has been already and how fast these innovations have arrived.

Our vision for the future

Now, as we look toward the future of R&D ten years ahead, we glimpse an entirely new vista: a world where drug discovery is driven by machine learning and advanced analytics mining large data sets, enabling us to understand and visualize interaction with targets and to predict in silico a molecule's likelihood of success and reach approval in the market. Among many other innovations, we will see mainstream use of real-world evidence (RWE) to demonstrate the efficacy, safety, and outcomes of products with regulators, payors, and providers; a new model for conducting clinical trials where patients are enrolled as part of their routine care and rich data is collected through non-

⁶ Jamie Cattell, Sastry Chilukuri, and Michael Levy, "How big data can revolutionize pharmaceutical R&D," April 2013, McKinsey.com.

interventional means to improve the speed, cost, and quality of operations; the widespread use of sensors to collect rich information continuously from patients, and the broad-based application of artificial intelligence and deep learning to diagnose and treat patients.

This is a world that is completely digital—not simply digitized. While the latter applies digital technologies to current approaches (for example, moving from manual processes to paperless systems), going digital requires a complete rethink: deploying digital technologies to reimagine value chains and drive new innovation. Done right, we believe the size of the opportunity is \$50-150 billion of EBITDA across the industry.⁷ Given the nature of R&D, we think this journey will unfold over the next decade.



Achieving this vision

What then needs to be done and how do we set about architecting the digital transformation to achieve this vision? We believe that there are three key areas of focus that will unlock success⁸: the first two concentrate on areas of disruption that will transform R&D productivity, while the third targets the technology processes, culture, and mind-set that will underpin this transformation at scale.⁸

- 1. R&D in the age of analytics. Companies that succeed at big data and advanced analytics outperform their competitors in every sector—for instance, Amazon in retail and Capital One in financial services—and we are currently at the start of the revolution in drug development. We see a wide range of use cases spanning R&D, including:
 - Mainstream use of real-world evidence for regulatory, payor, and medical applications
 - Use of data and analytics for next-generation clinical operations
 - Insights from in silico studies and analysis of diverse datasets to accelerate research and early development through more informed decision making, including smoothing the repurposing of existing drugs for new therapeutic areas
 - Building active surveillance capabilities to enhance pharmacovigilance (PV) operations and improve patient safety

⁷ McKinsey analysis.

⁸ Sastry Chilukuri and Steve Van Kuiken, "Four keys to successful digital transformations in healthcare," April 2017, McKinsey.com.

- 2. Connecting with the individual customers. It is no secret that the true impact of digital has been about reinventing the customer experience. Apple has successfully changed human behavior many times over, and technology winners such as Facebook, Netflix, Uber, and Amazon have simultaneously eliminated transaction costs while offering a delightful customer experience. A significant value driver within R&D will be reinventing how companies engage physicians, patients, and investigators at a granular level.
 - Through digital, medical affairs teams have the opportunity to understand the requirements of individual physicians (as well as other stakeholders) and to deliver precise information on demand.
 - Digital provides the opportunity to reimagine clinical trials around people. Patients will benefit from our greater understanding of their journey to improve their outcomes and trial experience including participation and adherence. Additionally, the use of wearables and other connected devices offers the opportunity to collect richer data automatically and enhance the experience of both patients and investigators.
 - Equally, adopting a partnership approach with investigators—understanding their specific pain points and deploying digital to streamline protocols and processes—will undoubtedly benefit sponsors in today's increasingly cluttered landscape of more complex trials.
- 3. Designing the digital transformation at scale. Most pharmaceutical companies are digital laggards compared with companies in other sectors such as media, retail, and telecommunications. Their digital-transformation efforts can stall for many of the same reasons these efforts are thwarted for others-for instance, a limited understanding of the specific ways that implementation of new technologies can create business value, a shortage of native digital talent, and insufficient focus on digital topics from senior leadership. Our experience with companies inside and outside the healthcare ecosystem suggests there are four core principles for succeeding with this kind of all-encompassing change program. First, healthcare companies (and R&D organizations) need to identify and prioritize their critical sources of value; they need to identify the capabilities that lead to competitive differentiation and those that would benefit most from digitization. Second, they must build their service-delivery engines-not just in managing new digital technologies but integrating agile, data science, and experience design into the fabric of the organization. Third, healthcare companies should look for ways to modernize their IT foundations: for example, moving to digital platforms such as cloud and Software as a Service, managing data and knowledge as a strategic asset, and improving security protocols for the company's crown jewels. Finally, companies must ensure that they build and maintain core management competencies including governance, financial processes, and organizational health-in other words, all the enablers that allow them to pursue a successful digital agenda.

These are the challenges and opportunities that lie ahead and we note that realizing the digital opportunity is no simple task—it represents a new innovation capability for the entire organization. What follows maps to each of these components to provide a broad-brush picture of how these momentous changes will play out in R&D over the next ten years or so, enabling us ultimately to plot a course through these uncharted waters.



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