Big Data *to* TRANSFORM R&D

The use of big data is expected to be a disruptive innovation for research and development.

The use of big data is expected to transform healthcare in general and the pharmaceutical in particular. 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 U.S. healthcare system, by optimizing innovation and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches.

Big data is expected to revolutionize research and development. Effectively using these data will help pharmaceutical companies improve the efficiency of clinical trials and better identify new potential drug candidates.

McKinsey's 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 (see box on next page).

New data technology will change how pharma and device product developers and healthcare providers make decisions, says Cinda Orr, president and CEO of Scorr Marketing.

"There is technology on the horizon that will give us the ability to apply data in three-plus dimensions from both numbers and semantics that continuously live and learn," she says. "Today, data are used to make acute decisions. Developers marry two sources of historic data to answer questions or solve problems. In a sense, a lot of decisions we make are obsolete the moment data are analyzed. Through innovative graph modeling and matrices using multiple sources of quantitative and qualitative data, we will be able to access knowledge and insight that isn't obvious with today's traditional methods. Technology will guide better and more future-focused decision making."

There will likely be increased adoption of integrated informatics platforms that allow pharma researchers to build workflows that span the drug development, preclinical, and clinical departments, says James Hayden, senior VP, global sales and marketing, Certara.

"While the number and complexity of pharma informatics solutions being used have grown, the drug failure rates have not improved," he says. "Many drugs are still failing late because the organization's discovery and preclinical data remain siloed, and researchers don't have access to all of the available data for many critical decisions."

Mr. Hayden says pharma companies need better options for organizational learning.

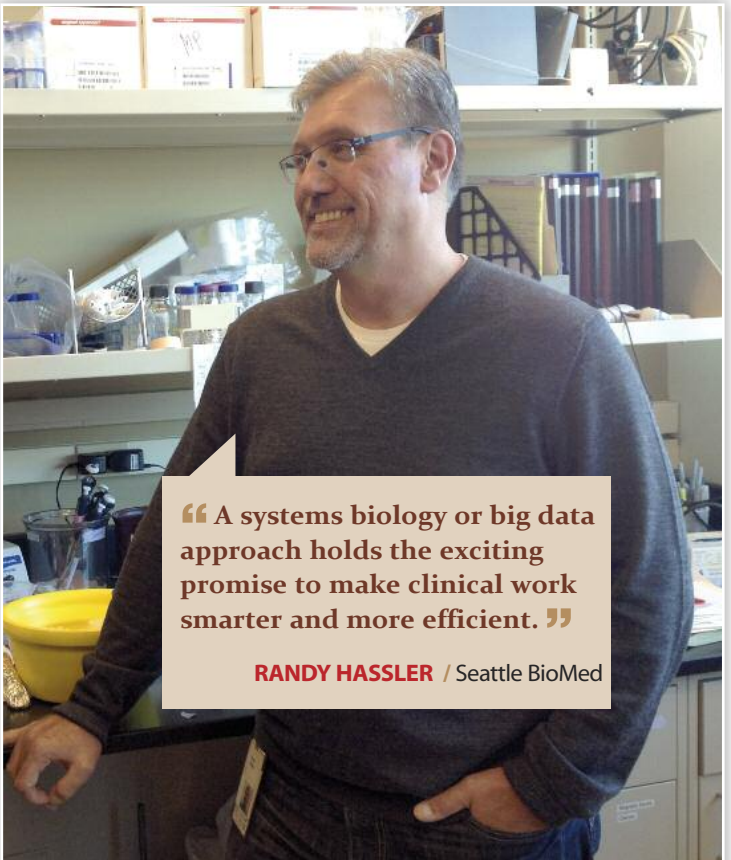
"There are instance when drugs fail in Phase II or Phase III trials but there is no mechanism for sharing that information upstream and there is nothing to prevent a similar molecule failing two or three years later," he says. "Pharma companies require an effective way to communicate between silos so that drug development and preclinical teams can learn to improve an animal model or use a different biomarker."

Raj Indupuri, executive VP, Technical Services, of eClinical Solutions, says adoption of technology and the evolving use of big data, cloud computing, and analytics are significant trends.

"Simply, the efficient collection of data and its subsequent ease of use will greatly impact R&D for our industry," he says.

Data are only as good as what can be done with it, Mr. Indupuri says, and the adoption and use of globally accepted standards will drive R&D efficiencies.

"Increased standards adoption with leadership from organizations such as CDISC and the importance of standardized data and its function throughout the development process can't be emphasized enough," he adds. "We believe a few important objectives, and corresponding challenges facing the life-sciences industry revolve around R&D productivity and the challenging regulatory environment. Increased agency requests for extensive study data and queries obviously drive research costs and at the same time decrease approved compounds. As companies are trying to find treatments or solutions to more complex, rare and unusual diseases, they continue to search for methodologies to become more efficient, streamline process, and reduce development costs without jeopardizing trial quality or risk-



> "A systems biology or big data approach holds the exciting promise to make clinical work smarter and more efficient."
>
> **RANDY HASSLER** / Seattle BioMed

> **"Big data will allow for the selection of patients before clinical trials based on a set of characteristics, including genetic profile and biomarker profile. This may lead to smaller trials with better responder rates."**
>
> **DANIEL TEPER** / Immune Pharmaceuticals

ing patient safety issues. With this in mind, we believe collaboration, operational efficiencies, and enhanced analytics are keys to meeting these overall objectives."

There are countless opportunities to improve R&D with big data, agrees Eric Silberstein, co-founder and CEO of TrialNetworks.

"The 'r' side was early to embrace big data before it was even called big data," he says. "Although the 'd' side has always collected a ton of data, it's not really big by big data standards. This will change. Two examples: assessment of endpoints via continuous collection of data, and DNA sequencing as part of clinical trials."

When considering big data in this space, it's important to consider the three Vs — volume, velocity, variability — which have different challenges and opportunities across development, says Paula Brown Stafford, president, clinical development, at Quintiles.

"These include clinical data captured within a trial, care data, including –omics, captured through EHR systems, and direct-from-patient data captured via social media and mobile devices," she says. "If the industry can embrace big data and transform it into advanced predictive analytics, then the industry's opportunities to optimize R&D are significant."

Big data will enable completely new methods of hypothesis generation and confirmations, says Rick Morrison, chief technology officer, Comprehend Systems.

"Companies will be able to use both historical and current data to understand their drugs, drug-drug interactions, and more," he says. "Big data platforms will allow real-time insight into ongoing studies to a level never before possible. This will enable studies to run more efficiently, cheaper, and safer."

For some, the term big data promises the answer to everything; for others it presents the ultimate informatics challenge, says Bryn Roberts, Ph.D., head of pharma research and early development - informatics at Roche.

"In life-sciences research and pharma R&D, we are grappling with big data as we try to understand the complexities of biology and the processes underlying disease," he says. "In this era of data-driven personalized healthcare, we must bring the world's knowledge to our scientists' fingertips, enabling them to harness the potential of big data to remain on the forefront of innovation and power decisions that revolutionize medicine."

Dr. Roberts says although the data volume available may be huge quantitatively, coverage and quality are often insufficient to provide insights to make sound decisions.

"That is where the design of experiments becomes so important in ensuring we generate data of sufficient quality and reliability to allow successful decision making," he says. "More importantly, the big data challenge in R&D requires a multidisciplinary approach where biologists, computer scientists, toxicologists, statisticians, chemists, and many others need to work in a highly collaborative way. By integrating data from many sources and formats, developing new approaches to visualize and explore very large information landscapes, and analyzing algorithms, we can enable scientists to extract meaning from massively complex data and also produce novel human-computer interfaces so that multidisciplinary teams can interact with their data more meaningfully and guide decision-making when moving projects forward."

Big data will allow for the selection of patients prior to clinical trials based on a set of characteristics, including genetic profile and biomarker profile, says Daniel Teper, CEO, Immune Pharmaceuticals.

"This may lead to smaller trials with better responder rates," he says.

Bhaskar Sambasivan, VP and head of life sciences at Cognizant, says big data can be used to improve site selection, patient recruitment, and improve patient participation.

The Big Data Prescription for Pharmaceutical R&D

Research done by the McKinsey Global Institute 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:** Data are the foundation upon which the 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.
- **Collaborate internally and externally:** By breaking the silos that separate internal functions and enhancing collaboration with external partners, pharmaceutical companies can extend their knowledge and data networks.
- **Employ IT-enabled portfolio-decision support:** To ensure the appropriate allocation of scarce R&D funds, it is critical to enable expedited decision making for portfolio and pipeline progression. IT-enabled portfolio management allows data-driven decisions to be made quickly and seamlessly.
- **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.
- **Deploy sensors and devices:** Pharmaceutical companies can deploy smart devices to gather large quantities of real-world data not previously available to scientists. Remote-monitoring devices can also add value by increasing patients' adherence to their prescriptions.
- **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 become increasingly adaptable to react to drug-safety signals seen only in small but identifiable subpopulations of patients.
- **Improve safety and risk management:** Safety monitoring is moving beyond traditional approaches to sophisticated methods that identify possible safety signals arising from rare adverse events.
- **Sharpen focus on real-world evidence:** Real-world outcomes are becoming more important to pharma companies as payers increasingly impose value-based pricing. These companies should respond to this cost-benefit pressure by pursuing drugs for which they can show differentiation through real-world outcomes.

Source: McKinsey Global Institute

> **"The integration of operational clinical data and past trial data can help drive better and earlier understanding of safety profiles leading to better product development."**
>
> **BHASKAR SAMBASIVAN** / Cognizant

> **"Fast, low-cost gene sequencing combined with advanced data analytics have the biggest potential for breakthroughs in the coming 12 months."**
>
> **TOM O'LEARY** / Icon

"Integration of operational clinical data and past trial data can help drive better and earlier understanding of safety profiles leading to better product development," he says.

Big Data in Personalized Medicine

Big data brings us closer to the goal of personalized medicines, says Sheila Rocchio, VP of marketing and product management at PHT Corp.

"Big data gives us more opportunities to build a more complete picture of the patients," she says. "In general, we can imagine having data about a drug in research or in actual use, in observational trials, and in a social context that can come together to give us a picture of the factors that make a therapy work or not work."

Fast, low-cost gene sequencing combined with advanced data analytics have the biggest potential for breakthroughs in the coming 12 months, says Tom O'Leary, chief information officer, at Icon.

"Today, a human genome can be sequenced in a few hours for only a few thousand dollars," he says. "Desktop gene sequencing has the opportunity to be used in routine diagnostics, leading to faster disease detection with more precise diagnoses. The ability to sequence patients together with all the bacteria and viruses that can cause cancer will enable a much better matching of therapies to patients."

Mr. O'Leary says big data that can link genotypes and phenotypes has the potential to be used to better stratify patients into groups in clinical drug trials.

"This will lead to better outcomes from clinical trials overall," he says. "This will be critical as the industry continues to move to personalized medicine."

A systems biology or big data approach holds the exciting promise to make clinical work smarter and more efficient, says Randy Hassler, chief operating officer at Seattle BioMed.

"By creating networks of biomarkers that can enable us to pursue more work on drugs and vaccines in a dish and better understand how those candidates impact the immune system even before putting them in people we can save millions of lives and dollars by only testing drugs and vaccines that we know have the potential to succeed," he says. "Rather than wasting time and money, we should be able to get better answers faster and cheaper."

Big Data Strategies

The potential of big data efforts in R&D is unlikely to be fulfilled unless organizations find a way to provide open access to their data sets, whether industry or academic, says Miguel Barbosa, Ph.D., VP, head, immunology research and scientific partnership strategy at Janssen Research and Development, part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

"As the term indicates, the potential value is correlated to the breadth and depth of the data set available for analysis," he says. "The reality is that more data are better than less data when it comes to yielding useful learnings with the confidence to support investment in their application. The challenge is to create the legal and business structure that supports broader data sharing in a compliant manner and with protection for the participating organizations. It is most promising that innovative models are being tested in the industry and academic R&D arena."

> **"Adoption of technology and the evolving use of cloud computing, big data, and analytics are three major trends."**
>
> **RAJ INDUPURI** / eClinical Solutions

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Systems biology and ways to capture big data are highly disruptive, and have major impact on how Seattle BioMed operates, Mr. Hassler says.

"By taking a big data approach and creating complex networks, we hope to answer some of the fundamental biological questions that have eluded us for decades," he says. "The challenges that accompany these exciting technologies are largely on the data management and analysis side, since they obviously have substantial technological requirements." PV

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