JPMSA
JOURNAL OF THE PHARMACEUTICAL MANAGEMENT SCIENCE ASSOCIATION

IN THIS ISSUE:

SPRING 2016

The Value of EMR Data: Unlocking Insights That Drive Pharma Sales

Steve Love, Principal, ZS Associates; Sudhanshu Bhatnagar, Business Consulting Manager, ZS Associates; Greg Rickman, Business Consultant, ZS Associates; Jedy Wang, Business Associate Consultant, ZS Associates

Abstract
Each step in the physician workflow creates data – and more of it is being created every day. EHR data vendors can now capture, aggregate, access, and analyze more data than ever before. New and different de-identified sources of data provide new and compelling insights and research capabilities, including real-world evidence, which enhances findings beyond those from the original small-scale FDA-approval trials. Real-world case studies reveal that by applying deeper data analytics than ever before, pharma can use this new realm of data to uncover insights that help guide them toward more-successful sales and marketing efforts.

The pharma industry has an endemic challenge. It has a complex and circuitous sales process involving drug manufacturers, physicians, pharmacies, patients, and insurance companies. Each step in the buying process creates data – and more of it is being created every day.

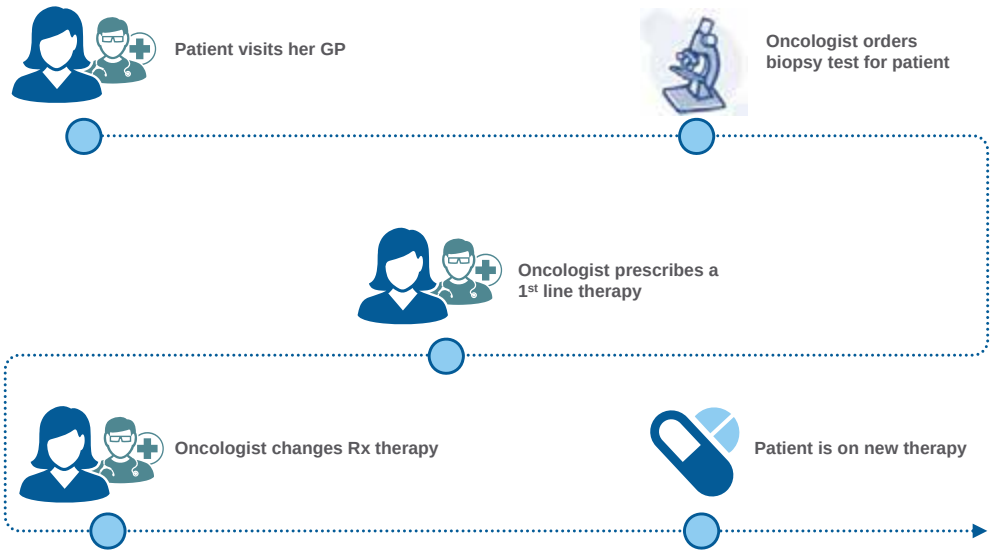
Arguably, pharma companies have always had access to these data through a variety of sources, including primary market research, but only some of the data have been readily available in large quantities. For instance, back in the 1990s, they had access to prescription and co-pay data through reimbursement claims. In the 2000s, they gained access to longitudinal claims data by tracking clinical visits, diagnoses, and prescriptions.

In truth, though, even having access to some of the data in large quantities from these sources has been problematic, because it's been siloed, fragmented, incomplete, and in differing formats. Getting a holistic view of the entire patient journey through primary market research has been expensive, time-consuming, and potentially subjective or idiosyncratic (because of small sample sizes).

But there's a new opportunity for pharma, one that will change the way they think about data, its aggregation, and its analysis. The proliferation of EMR analytics and software platforms and the data vendors that now aggregate and sell the electronic health records (EHR) data warehoused in them, now give pharma companies greater visibility than ever into its marketplace of buyers, consumers, and decision-makers — and the factors that drive sales. Now pharma can research its markets by combining EHR data with traditional secondary data to see the entire buying process at a much larger scale than ever before. For the first time, pharma can use EHR data to supplement primary market research, taking advantage of the latter for its nuanced insights and the former for its breadth.

EHR data vendors can now capture, aggregate, de-identify, access, and analyze more data than ever before. New and different sources

Figure 1: Examples of Patient Level Data Available From Claims



of data provide new and compelling insights and research capabilities, including real-world evidence, which enhances findings beyond those from the original small-scale FDA-approval trials.

Consider these opportunities of EHR data:

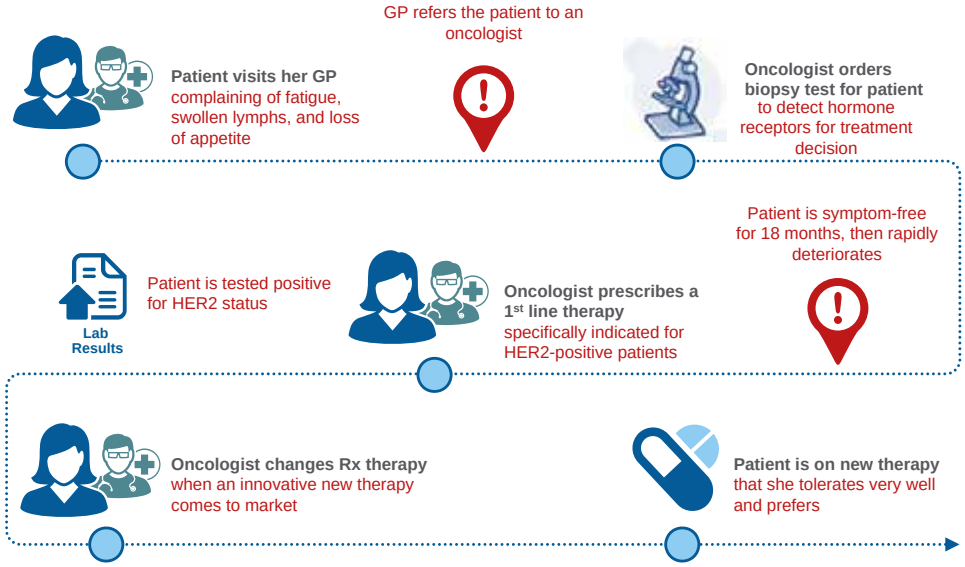
- The ability to better understand when products are used, including how, when, where, by whom, in what circumstances, dosage, and frequency
- The ability to understand when products are *not* used, why not, and which competitor made the sale
- The ability to transform insights gained by analyzing EHR data to make better strategic decisions, including how to identify and win against competitors, and how to identify which segments (indications, patients and MDs) to target for highest profitability
- The ability to make better tactical decisions; that is, what actions to take to execute strategic plans, and to identify best sales and marketing methods

Pharma finally has a new way to collect and view information that was previously very expensive to obtain manually or only available on a much smaller scale. The industry now has the unprecedented opportunity to understand testing and treatment decisions, patient outcomes, the decisions being made at each step, and determine – finally – how it might influence in its favor.

What's New: The EHR Data Vendor Landscape

Two important advances are helping pharma discriminate a new generation of marketing insights. In addition to using primary market research and claims information, pharma now has access to anonymized patient-level EHR datasets. These records include other data points with greater granularity. The spectrum of data is almost unprecedented: lab results, diagnoses, prescriptions, patient compliance, physician notes, and follow-on or replacement prescriptions. Overall, these results can map the entire course of a disease and its treatment through cure or death.

Figure 2: Examples of Patient Level Data Available From EHR



While there are more data sources, there are also more ways to make the data useful. Thanks to technological advances, it's now easier to (1) capture, (2) aggregate and de-identify, (3) standardize, and (4) analyze more volume of data. New analytic tools and capabilities allow better ways to aggregate and integrate both claims and EHR data, for deeper analysis. These tools can convert unstructured data (i.e. physician's written notes) into structured data to expand the depth of information captured. As a result, companies can increase the breadth of the information they use for analysis.

A Sample Scenario

To better understand the ways in which pharma can use both new information and new analysis techniques, consider the example of a patient visiting a primary-care physician. A claims data study would only reveal certain aspects of her treatment: that the patient initially visited her primary care physician; that a pathologist ordered a subsequent biopsy; and that one or the other prescribed medication. (*Figure 1*)

But there is a large amount of important additional data that EHRs can add to that picture, more simply and economically than via primary market research. For example, the EHR would likely reveal what prompted the patient to make the initial visit: complaints of fatigue, swollen lymph nodes, and loss of appetite. It would also reveal how the primary care physician responded, whether by running diagnostics tests or by referring her to an oncologist. (*Figure 2*)

EHR data also reveals why the pathologist ultimately ordered the biopsy test, such as to detect hormone receptor status and other genetic biomarkers, which would influence the treatment decision. It would reveal the results of the lab test, including a positive test for HER-2 status (a diagnostic biomarker for breast cancer), which would in turn give insight into why the oncologist prescribed the drug therapy: because it was specifically indicated for HER-2 positive patients, and because its safety profile was the best fit for the patient's comorbidities.

In this scenario, EHR data also reveals that the patient responded to first-line therapy for a duration of 18 months, after which the patient's condition deteriorated. It also illuminates the thought process behind why the oncologist changed the drug therapy; it could have been in response to multiple issues, whether a new drug launched, patient characteristics, disease characteristics, or non-clinical (i.e., financial) reasons.

Finally, the EHR would also show how the patient responded to the new therapy, revealing such details as either patient preference (based on different, or lack of, side effects) or the fact that the disease did not progress for 18 months. All that information is now accessible across thousands of patients to provide a market level (vs. patient level) view of that therapy area's marketplace.

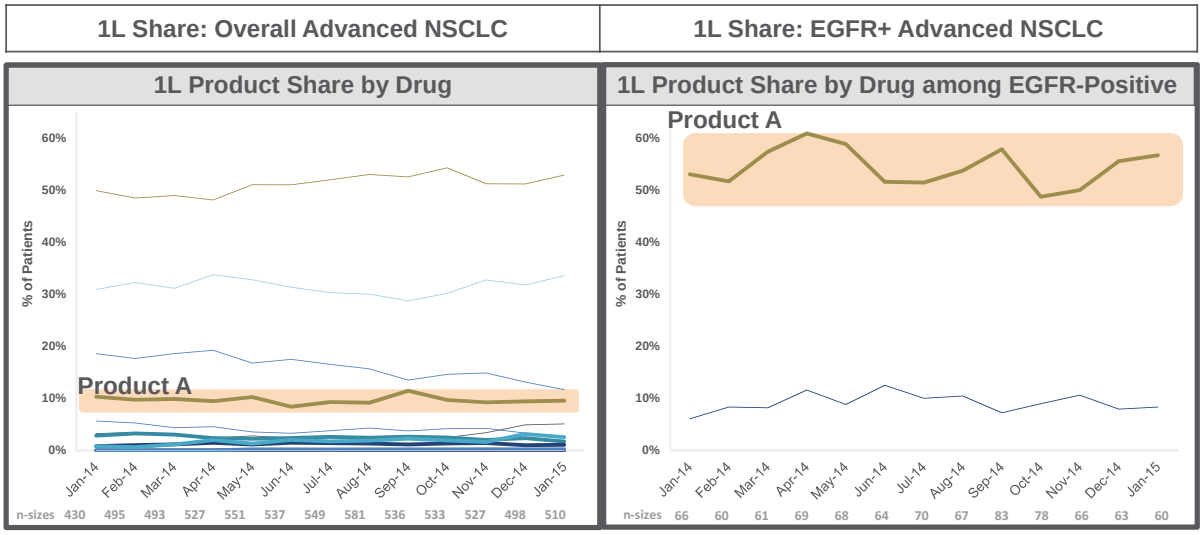
The previous scenario is for illustrative purposes, but vendors are already creating opportunities for data usage based on four different business models:

- Some vendors source their data exclusively from their own proprietary (or leased) EMR platforms themselves. Other vendors are EMR- agnostic and integrate EHR across multiple EMR platforms.
- Vendors may differ in their focus on therapy areas — looking only at primary care diseases, specialty areas, or a combination of the two.
- They may also differ in their emphasis on data provision only, analytics, and/or providing point-of-care information services.
- Some companies sell discrete data sets designed to answer specific questions at a point in time, while other vendors sell subscriptions to entire databases that allow for perpetual analyses of the subscriber's choosing.

Efficacy in Three Case Studies

There are many actual examples of transformative applications for EHR data. Consider these three real world case studies in which EHR data vendors delivered valuable market insights for their pharma manufacturer clients. They come from three leading data vendors: EHR data vendor Flatiron Health processes both structured and unstructured EMR data for considerably improved accuracy in patient and disease characterization and completeness of data elements provided; EHR data vendor Practice Fusion offers clinical guidelines and best practices to providers specifically for patient encounters, allowing practitioners to search on critical patient metrics within their records; EHR data and analytics vendor Optum-Humedica focuses on health economics and patient-report outcomes research, especially in the area of pharmaco-epidemiology.

Figure 3: Example No.1



By analyzing monthly updates of longitudinal patient-level EMR data that included access to deep biomarker testing and results over a twelve-month period, a pharma company was able to determine that its product had a much larger market share within a specific patient sub-segment.

Example No. 1

Context: A pharma company wanted to understand patient share within the population of EGFR mutated advanced non-small cell lung cancer patients. Historic data sources presented challenges with regard to completeness of biomarker data and/or data recency. (*Figure 3*)

Action: The patient level data provides a complete view of each patient with resolution into diagnosis, stage, histology, testing, test result, treatment and patient outcomes. Based on analysis of Flatiron's data, the customer was able to determine that the patient share for the therapy was 50-60% in the target biomarker population.

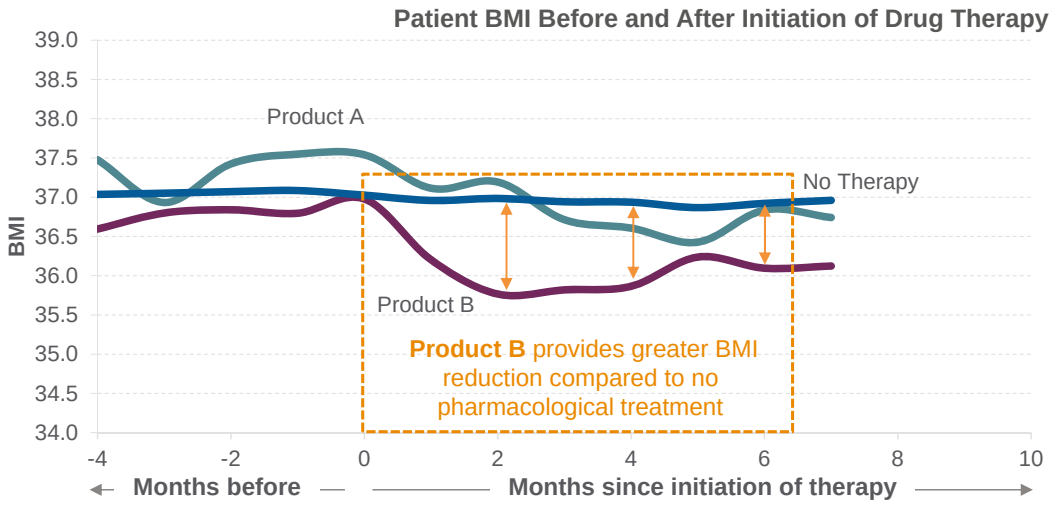
Recommendation: The delighted client was able to conclude that they were the market leader for the indicated patient population, but also that there was still a significant growth opportunity in its target segment. The client used the EMR data output to improve the company's understanding of testing, treatment and outcomes for specific patient segments, and improve quality of its forecasting model for the indicated patient population.

Example No. 2

Context: A pharma company wanted to prove the efficacy of an obesity medication compared to competitor's drugs and non-pharmaceutical interventions alone. (*Figure 4*)

Action: Practice Fusion used its own research database and compiled the results from the following samples: 2,003 patients using Therapy A; 3,104 patients using Therapy B, and 16,200 non-therapy patients with high BMIs. Analysis revealed that after two months, the company's obesity drug reduced patients' average BMI by 1.5 points. EHR data also revealed that the client company's drugs were more effective than its competitor's drugs and a non-therapy solution. The data illustrated the real-world results at different time intervals both before and after initiation of therapy.

Figure 4: Example No.2



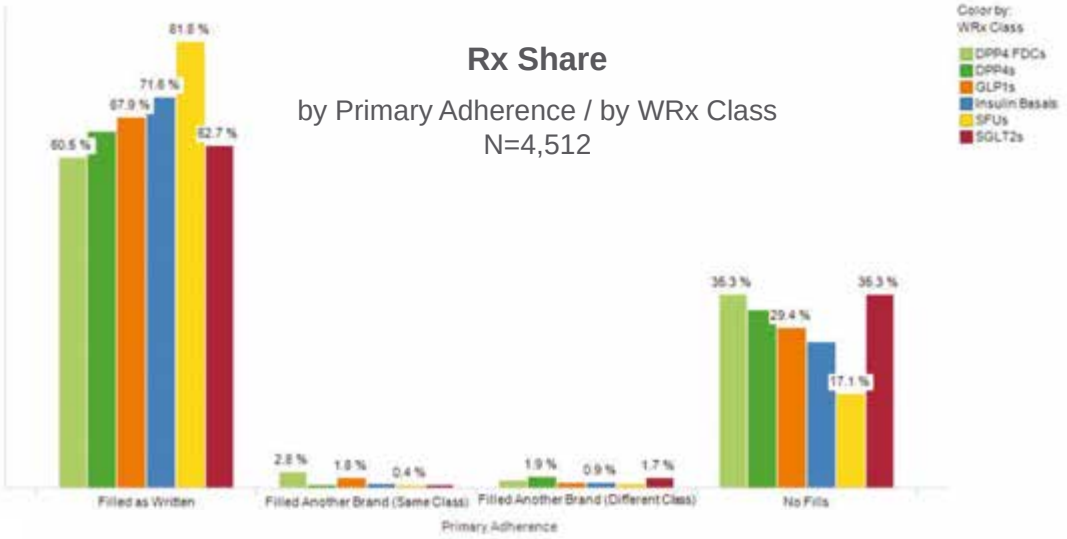
By analyzing data from thousands of patients in its research database, data vendor Practice Fusion was able to show that Product B provided greater BMI reduction than both a comparative product and no pharmacological treatment at all.

Recommendation: These results enable a drug manufacturer to demonstrate to payers the real-world efficacy of its drug and improve its business case for higher formulary status. In addition, these results could also be combined with other results, such as A1c, cholesterol, and blood pressure, to show how holistic the impact of the drug can be in real-world settings.

Example No. 3

Context: A pharma company wanted to study whether diabetes patients were adhering to the therapy regimens prescribed by their doctors. (*Figure 5*)

Figure 5: Example No.3



Analysis of claims data in conjunction with chart information revealed that within three months, as many as half of patients had stopped taking the diabetes medication, indicating a need for reallocation of marketing resources.

Action: Optum-Humedica combined claims and patient-level chart information from a de-identified sample size of 4,512 to discover an intriguing fact. Although high percentages of patients filled the initial prescriptions as written – especially in comparison to other brands – within a three month period, as many as half of patients had stopped refilling their prescriptions. This insight wasn't available in claims data, because claims only show what happened, not what the physician intended to happen. The analysis revealed that although the pharma company thought it had achieved its sales goals, it had actually only accomplished part of them.

Recommendation: The data revealed that although the physician wrote the prescription, and the payer reimbursed for the drug, the patient didn't continue taking the medication as prescribed. The data helped the pharma company reallocate its marketing resources to solve a problem that it didn't even know it had! The vendor was able to compare physician intent versus prescriptions actually filled, and adjust payer outreach and/or patient marketing accordingly. The results also showed that the longer a patient took to fill a prescription, the less likely they would fill it with the prescribed brand. By understanding how frequently patients turned to generics, the vendor was able to address the opportunity for increasing first fills of its own product.

A Caveat: Challenges Remain Before Getting To This Level of Insight

Though pharma companies have high potential to gain new insight, there are some caveats to remember, in the form of distinct limitations.

Data limitations. Even in this data-driven age, the capture rates of practices can be limited, depending on the disease area. Biases toward collecting data may exist, based on types of practices, their geographies, or other issues. At the same time, data sets can be incomplete and difficult to analyze due to a lack of standardization in how workflow inputs are collected or how EMR platforms exchange data. And robust longitudinal data can be difficult to find because patients move to different HCPs – and their different EMR systems.

Technology limitations. The challenge of integrating data has baffled experts for years, and while new analytic tools available under the rubric of "big data" represent a step forward, they are new and not yet perfected (ditto natural language processing systems used for data extraction from unstructured fields). It's only recently that companies are able to wrest meaningful insights from the piles of data, and it may take a while to get proficient at it.

Vendor limitations. EHR data vendors have unique focus areas and data sets, as well as different products and sales models (subscription to real-time data platform vs. discrete data set; raw data vs. analytics).

Moving Forward

In the face of this potential – and potential pitfalls – what can pharma companies do to increase the value of EHR data in the future?

In the short term, they can be better informed about both the benefits and tradeoffs of EHR data, and they can also start building up their EHR data analytics capabilities. In the long term, they can identify EHR partners best suited to answer their business questions, and incorporate EHR data insights to drive better sales and marketing decisions.

Either way, the key is to start thinking about these issues now. Only those who understand its ramifications and value early will derive a strong competitive advantage in the long term.

Sidebar: Q&A: What Pharma Needs to Know About EHR Data Vendors

When pharma companies embark on programs to understand the value they can derive from the analysis of EHR (electronic health records), it's important to understand the data vendors and how the market is changing. Here's a Q&A to help pharma understand what it needs to know about the current state of the EHR data market.

Q: What changes can we expect to see in the market?

A: The market will continue to undergo shifts in business models and technology. Vendors who sell EMR platforms will be particularly affected the most, especially from the standpoint of market consolidation. Historically, some platform vendors had difficulty accommodating Stage II meaningful use requirements, which led to a wave of consolidation, and the Stage III meaningful use standards are even higher. From a technology standpoint, most EMR companies are moving to the cloud-based operating model (data managed centrally on the cloud) and away from an on-premises model (data resides on the EMR instance on local office/hospital); this is operationally more cost effective and also scalable from a data management perspective.

Q: How are pharma companies collaborating with companies that sell EHR data?

A: Companies are actively innovating with pharma manufacturers to provide new data analytics and point of care services. For example, two companies have partnered to invest significant effort and resources on NLP techniques to systematically extract information from unstructured physician notes and other text-based fields. Another is the creation of EMR patient portals (patients opt-in by default) that collect patient feedback on issues such as reasons for discontinuing treatment.

In addition, EHR data vendors are collaborating with ACOs to provide real-time data at point of care to improve the ACOs' quality metrics. For instance, at least one health intelligence platform can also help pharma leverage EMR data to analyze performance relative to ACO measures. For example, if one of the ACO measures looks at the percentage of diabetic patients with A1c who are not reaching their goals, pharma can both proactively identify those specific patients (in order to get them into a more-intensive diabetes management program) and then segment that data across the entire health system, taking into account sites of care, regions, and individual providers.

Q: Why is it important for pharma to have a better understanding of these applications?

A: The line between commercial and medical applications is blurring. Datasets used by health economics and outcomes research (HEOR) and commercial groups at Pharma companies are becoming one and the same, i.e., commercial groups are getting more sophisticated and mindful of outcomes, while HEOR groups are more interested (or concerned) about aligning with the commercial impact.

EHR data companies, in particular, believe that their data, although only a partial sample, is fairly representative of overall national trends, based on comparisons with other data benchmarks. Insights from these applications could be used for national level metrics estimation, although the ability to execute

sub-national analysis depends on the therapy area and how quickly the n-counts decrease.

Q: What other value can pharma derive from these applications?

A: EHR data vendors are continuously looking to integrate their data with other external datasets and potentially with other EHR vendors' data — if there is a significant push from the manufacturers. This integration and increasing subscriber base will make EHR data significantly more valuable to pharma companies commercially as well as for outcomes research.

For instance, companies are collaborating with claim data vendors to de-identify patients and link their information – to make more robust longitudinal datasets (more so with closed claims vs. open claims vendors). This integrated data overcomes one significant drawback of EHR data when patients change insurance companies, because EMRs using a unified patient ID will still be able to track anonymized patients. Neither EMR platform companies nor EHR data vendors are actively looking to make this investment without sufficient incentives, but are open to try if the pharmaceutical consortium will help carve a path forward.

About the Authors

Steve Love *is a Principal with ZS Associates in the San Francisco, CA office and the Tracking Practice Area Leader for ZS. His experience at ZS over the last 14 years has focused on a variety of market research studies and business analytics using secondary data such as EMR. Steve has led many marketing engagements with emerging and large biopharmaceutical companies, particularly in oncology. Steve holds an HBA from the Richard Ivey School of Business at the University of Western Ontario and an MBA from the Haas Business School at the University of California Berkeley.*

Sudhanshu Bhatnagar *is a Business Consulting Manager with ZS Associates in the San Francisco, CA office since 2007. His primary focus is on the biotech and medical device verticals and he has advised clients on improving their commercial effectiveness including sales organization design and enablement, launch planning, marketing operations and business processes optimization, including focus on commercial data analytics. Sudhanshu holds a Bachelor of Engineering from University of Pune (India) and is pursuing his Executive M.B.A. from the Wharton School of the University of Pennsylvania.*

Greg Rickman *is a consultant with ZS Associates in the San Francisco, CA office and has 3 years of experience in healthcare consulting, including working in PWC's Health Industries Advisory practice prior to joining ZS. Since joining ZS, Greg has focused on qualitative and quantitative primary research and commercial strategy for large, global biotechnology clients. Greg earned his BA from Princeton University and an MBA from UCLA Anderson School of Management.*

Jedy Wang *is a business associate consultant with ZS Associates in the San Francisco, CA office. She has worked as a consultant in the healthcare industry for 4 years with a focus in market research, secondary data and EMR analytics for emerging and industry-leading biopharmaceutical clients. Jedy holds an HBA from the Richard Ivey School of Business at the University of Western Ontario.*

www.zsassociates.com