A Look Ahead to 2014-2016:
Scientia Advisors
Scientia Advisors believes that the next few years, while challenging, will present some of the best business opportunities in decades for industry participants around the world. We came to this belief after participating in thousands of meetings and conversations, over the past year, with key opinion leaders, clinicians, researchers, regulators, payers, and providers from around the world.

It comes as no surprise to anyone in the industry that cost pressures are at an all-time high, particularly in the developed world. Although the European community has been focusing on costs for a longer period of time, the US move toward value-based purchasing, decline in breakthrough treatments, and increasing member cost share (through copayments and deductibles that enable consumers to directly feel the impact of health costs) has accelerated the demand for increasing value in healthcare.

This is not to suggest that innovation isn’t valued. Quite the contrary. While innovation will always be an essential part of any long-term successful enterprise, partnering it with “value” is going to be the winning formula in the coming years. Whether for the patient, payer, provider, or clinician/researcher, the need to demonstrate measurable and enduring value will be the basis of global competition. Technological innovation and increasing data analytic capabilities, along with studies by NICE in the European Union and payers/providers in the United States are facilitating this trend. Electronic health records (EHRs) are laying the foundation for more to come.

Defining value

The term value has different meanings to different stakeholders. To a patient with a terminal disease, value can be measured in increments of disease-free progression and quality of life. To the clinician, value can be measured by better outcomes for each patient from a diagnostic, medical device, drug, or biologic within a predefined budget for treatment. To the payer and provider, value can be measured by the reduction in cost to treat a given patient or class of patients with higher customer satisfaction. None of this is radical to those outside the healthcare and life science industries, but for those inside, this represents a seismic shift in getting a product to market and ensuring maximum access for the appropriate patient population. Even for products designed to be sold directly to the consumer (eg, 23andMe), proving empirically that they are providing clinically validated value to the patient will be paramount to obtaining FDA approval.
Given this increasing emphasis on “value,” here are some industry opportunities we see in the coming years.

### End-to-end solutions versus specific tools and point products

Payers and providers can’t afford to pay for “point” technological innovations, such as the latest minimally invasive catheter or pharmaceutical, merely because they offer incremental benefit. Instead, payers and providers are demanding that innovators demonstrate broader solutions to a disease condition that achieves their objectives.

It will not be sufficient, for instance, to offer only a pill. Instead, successful pharma companies will also facilitate improved patient adherence and ongoing monitoring capabilities for the payer and provider for their specific patients (not just clinical trial information). Sanofi’s portfolio of diabetes solutions, including the iBGStar® Blood Glucose Meter, GoMeals® meal and activity planning app, and A1C Champions®, a patient-to-patient education program, are great examples of how this trend will likely manifest itself. It is better to be proactive than reactive.

Data, or at least the facilitation of data gathered from products like Proteus Biomedical, on the success of a drug for a patient in the real world will become a requirement in demonstrating value. In fact, we expect that discussions surrounding big data will shift from infrastructure requirements in 2013 to algorithm development and real-time data mining in 2014. The entire value discussion will move from the “quantified self” (a reference to healthy users of self-monitoring consumer gadgets) to the “quantified patient” as drug, device, and diagnostic companies begin to release end-to-end solutions to their customers rather than specific tools or point products. Several leading indicators from which we will see more activity over the next few years include enhancements in analytics, data visualization, data privacy, data security, and increased partnerships between payers/providers and the industry.

### Genomics will follow the trend of democratization

Although centralization of laboratories and testing was the mantra of the last decade, the mantra for this decade is to provide patient access and care at a lower cost (particularly for routine care). A decentralized/democratized movement is occurring as companies like GnuBio, Life, Illumina, and Qiagen, among others, have begun offering solutions to small- and medium-sized providers to enable them to stay competitive with large academic and network providers. We are seeing this trend even in fields as complex as genomics and oncology. As the computer industry witnessed the shift from mainframes to mini computers to PCs, advancements in technology (eg, computing power, data visualization, bioinformatics, cloud computing) are enabling a similar shift to decentralized solutions that previously were only available to large labs and academic centers. Value, in this case, may not be defined specifically as lower cost, but as convenience, access, patient capture, and other nondirect economic issues that drive these decisions.
While we are cautious about reimbursement for home-based diagnostics in the coming years, we see a trend toward comprehensive diagnostic testing in retail clinics (eg, Walgreens and Theranos) becoming more pronounced. We need only look to France to understand that this trend is global.

The promise of health information technology (HIT) will be fulfilled: Clinical decision support and big data analysis become a reality

Despite years of waiting for HIT to change the practice of medicine, the next 2 to 3 years will finally enable the realization of this vision. After tens of billions ($US) in investment in EHR systems in the United States, Europe, and parts of Asia over the last 5 years, there are finally signs that EHRs are ready to be put to use in optimizing clinical decisions.

Hundreds of companies are looking to unlock the unstructured data in EHRs (eg, notes, reports) in order to generate insights into their patient population. The approach, often referred to as big data, is a massive amount of information that can be interpreted through analytics to understand underlying trends by pulling data from the EHRs. Something that would not have been possible in the past.

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China becomes a larger force in the industry

Regulatory requirements (many warranted) and increasingly longer patient enrollment cycles are going to lead to changes in the way devices, drugs, and diagnostics are tested and deployed. In 2013, Scientia Advisors saw many large and small clients driving clinical trials from major academic centers in the United States and Europe, by blending their patient test populations to include many more subjects from China (sometimes up to 90%). Whether US or European regulatory agencies will accept these data as being sufficient for trials is unclear, but what is clear is that China’s ability to help execute timely trials is unrivaled.

We pose the question, particularly as the Chinese government continues to make significant investment in healthcare R&D and clinical effectiveness, as to whether it will be long before a major drug, device, or diagnostic will first be launched in China versus the United States and Europe. That would certainly be a turning point for China, but would also have ramifications for the United States and Europe. If an initial product launch in China does occur, it would likely force a review of the US and European regulatory methodologies, which could in turn lead to streamlining of today’s processes.
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As noted in the New York Times earlier this year, big data is being used to increase post-marketing pharma company vigilance. Randomized clinical trials (RCTs) are currently considered the gold standard for research despite the fact that analysis and publications can take 6-8 years to complete. Although RCTs have been the best thus far, this method is too slow in determining new side effects or adverse events. A recent report by Dr Russ B. Altman and Dr Nicholas Tatonetti,1 conducted entirely with data already mined from 3 different EHR databases, detected a significant increase in blood sugar in patients who simultaneously took Paxil®, an antidepressant, and pravastatin, a cholesterol-lowering drug, despite the fact that, as a standalone, neither produced this side effect. We believe that the recent investment spree by the venture community in analytic-based companies is going to make this research methodology commonplace.

Another example of the increased use of data to drive clinical decision making occurred earlier this year and involved a collaboration between IBM’s Watson technology, WellPoint, and Memorial Sloan-Kettering. This collaboration produced the Interactive Care Insights for Oncology application to provide advanced clinical decision support systems for oncologists. After ingesting more than 600,000 pieces of medical evidence, 2 million pages of text from 42 medical journals, and numerous clinical trials in oncology research, the system will help oncologists and researchers identify the best treatment options for cancer patients directly from their EHR and facilitate prior authorization. The product is still in testing and will take some time before wider deployment. Yet, it is a meaningful milestone in clinical decision support systems (CDSS), something that has been discussed since the 1960s. Given the complexity of genomics, pathology, immunology, and oncology, among others, we see the need for data trending toward more and more CDSS applications over the next few years.

Reverse outsourcing

China has recently become fertile ground for providers looking to expand their businesses. Major institutions such as Massachusetts General Hospital and The Cleveland Clinic are providing advanced services remotely (reverse outsourcing). US and European pathology departments are using e-Pathology systems (often not even in widespread use within the clinical practices of their own institutions) to enable remote readings. Until China can produce enough clinicians and specialists to keep up with demand, these types of outsourced services will only become more pervasive.

Clearly, these are only a few of the major trends that Scientia Advisors sees on the horizon. Our deep expertise from the bench and the boardroom enables the Scientia team to offer advice across the spectrum of healthcare, life sciences, and the pharmaceutical industries. Please contact us to begin the conversation as to how we can help your strategic and operational needs in 2014 and beyond.

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