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## **Innovation in Today's Transforming Healthcare Environment**

### **Three Tactics for Survival**

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Everyone knows the healthcare industry is changing in dramatic ways. The movement toward an outcomes-based, patient-centric, cost-conscious environment is well underway. The question for manufacturers of diagnostic devices and other clinical laboratory systems is how will this shift impact them—and what do they need to do to compete effectively, maintain or grow market share, and stay profitable?

Based on our experience working with innovators across the laboratory and diagnostics segment, we believe there are three key factors to succeeding—indeed, to surviving—in the transformed healthcare environment taking shape.

#### **1. Get Closer to the Patient, Get Smaller**

New patient-centered care models and the intensifying drive to accelerate care decisions and increase efficiency are reframing traditional ideas of testing. The lab must extend its reach out to patients, wherever they are. Point-of-care testing (POCT) is moving beyond the walls of the hospital or clinic into the community and even into patients' homes as patients and their caregivers become more empowered by technology. This is true both in developed markets and in emerging markets, where the healthcare infrastructure is less evolved and central labs may be few and far between. Indeed, these underserved markets offer tremendous growth potential for companies able to meet the demand for solutions that are simple, reliable, fast, and affordable.

This growing move to near-patient testing is driving demand for products that are smaller and simpler to use, while still enabling the lab to monitor test quality and results. To capitalize on this trend, device makers face a range of technical challenges. They need to miniaturize their products, while maintaining robust functionality and accuracy. They need to rethink user interfaces to ensure “fool-proof” use by operators who may have minimal training—or no training, in the case of devices designed to be used by patients themselves. Developing simpler, more intuitive interfaces is especially crucial in today's global marketplace, where products have to meet the needs of users speaking different languages, with different healthcare systems and cultures, different certification regimens, and widely varying levels of experience.

Device and equipment makers also need to think carefully about how their products will maintain connectivity to the central lab and its data systems. This could mean developing wireless connectivity, a base station with centralized data management capabilities, or cloud-based data management. Making sure test results are delivered to a central repository securely, reliably and with data integrity is critical for maintaining quality and compliance—and for ensuring all-important reimbursement.

## 2. Big Data Analytics, Big Opportunity

As the volume of healthcare data—including test-related data—explodes, its potential to create value multiplies. This is creating opportunities for makers of diagnostic devices and lab systems to add value to their products with next-generation data integration strategies.

Integrating the right analytics can enable a wide range of value-added capabilities that can improve test utilization, pattern identification, and throughput. Analytics can be used to streamline and improve processes—supporting better test utilization based on ordering patterns and faster throughput by analyzing workflows, for example. Another exciting area of innovation is the emergence of test algorithms that automate the selection and ordering of follow-up tests based on analysis of initial test results, accelerating workflows and improving quality of care. In the new healthcare era, time and money are both valuable commodities; critical care decision support helps make the most of both.

Test data can also play a role in clinical decision support for individual patients or in epidemiology analysis when aggregated with data from other patients. With the shift to value-based care and outcomes-based billing, data analytics will also play a key role in substantiating reimbursement claims and compliance with quality standards, such as the new CMS Individualized Quality Control Plan (IQCP) option for meeting CLIA quality control requirements for non-waived testing.

All of these analytics applications offer tremendous potential for differentiating lab devices and generating new revenue streams. But they require that equipment makers think carefully about data in all dimensions—from data collection and aggregation to advanced analytics. That means asking some important questions.

How can you harvest the data generated by your device to add value? How do you ensure you have a platform that supports applications that leverage similar data? What types of analytics would add value—and which stakeholders (providers, payers, patients) will derive the greatest value from those analytics? How do you demonstrate that value, including supporting meaningful use? Addressing these and other fundamental questions is critical for manufacturers to successfully extend their offering higher up in the value stack by integrating analytics into their solutions.

### 3. Business Model Innovation

Clinical laboratory device makers find themselves at a crossroads. Hardware is rapidly becoming a commodity. To prosper in the new healthcare landscape, they need to focus their innovation investments with an eye on the business models that will drive growth in the transformed healthcare landscape taking shape now. Those business models will emphasize the role of data as a generator of value. While accuracy, ease of use and affordability continue to be essential, a key differentiating factor will be how a product manages, distributes and utilizes data to help improve and accelerate clinical decision-making. Leveraging data intelligently enables clinical laboratory equipment companies to move beyond the traditional consumable-based model and create new revenue streams.

This shift requires that manufacturers adopt a systems thinking approach that looks beyond one's device at the larger "system of systems" environment. The goal of this approach is the synthesis of a whole product solution, rather than focusing on a system decomposed into solution components. Systems thinking is software-centric, rather than hardware-centric. It embraces the blurring of lines between medical devices and information systems. It emphasizes "connectedness" and recognizes that value is created through integrated architectures that enable interoperability and information exchange.

Software is at the core of this approach. It is the "glue" that holds these "systems of systems" together and enables higher-order capabilities. And it's the door that opens up the unlimited potential offered by disruptive technologies—like the cloud, mobile communications, and big data—that are transforming business models across the industry spectrum.

Shifting to a systems thinking approach isn't always easy. It requires that equipment manufacturers step out of established ways of doing things. It may also require expertise and experience that isn't available in-house. Overcoming these barriers can be simplified by bringing in an outside partner with specialized knowledge and a proven ability to apply systems thinking to clinical laboratory challenges and platforms.

#### Move Forward, Move Now

As the healthcare industry continues its rapid transformation, the implications are significant for the systems and solutions laboratories rely on to fulfill their role in the continuum of care. Delivering solutions that streamline and simplify testing while maintaining quality, improving outcomes, contributing to population health management, and moving up the healthcare value chain is crucial. And while hardware is still a critical factor, it is being rapidly eclipsed by software as the key differentiator and value generator.

To remain competitive, laboratory device manufacturers need to rethink traditional approaches. That means extending beyond the lab and getting closer to patients who

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are becoming more engaged and empowered through technology. It means leveraging the data generated from an expanding range of sources with analytics to drive new insights that can improve lab processes and patient care. Finally, it means focusing investments on innovations that enable the expansion of business models fueled by data and software that incorporate a holistic systems engineering approach to product realization.

For many equipment manufacturers, the greatest obstacle to successfully exploiting these opportunities is insufficient experience and expertise in the specialized areas of technology and strategy required. Working with a partner who has both medical domain experience and expertise in advanced data technologies, together with a systems-level perspective, can help equipment manufacturers achieve the “big step” changes that enable transformative growth.

Clayton Christensen, author of *The Innovator’s Dilemma* and *The Innovator’s Prescription*, has shown that being slow to react to disruptive changes in technology and embrace new market opportunities leads to failure. The dramatic changes impacting the healthcare marketplace are upon us—and the time to move forward is now.