

# LIFE SCIENCES TRENDS REPORT

2017

Undeniably, we are in a time of dynamic change and upheaval for the life sciences industry. Longstanding pressures for patient-centricity and value-based care have come to a head, forcing life sciences companies to rapidly adopt capabilities and strategies to demonstrate their commitment to the patient. Adding to that, the promise of big data, analytics, and digital solutions is no longer enough – stakeholders are demanding the actualization of these capabilities to broaden and improve therapeutic value. Meanwhile, mergers, acquisitions, and divestitures continue at a steady pace with deal value ballooning while volume declines. Organizations are approaching these deals with precision and meticulous consideration for growing “beyond-the-pill” value. These shifting dynamics have irrefutably created challenges for the industry but more so, they’ve created enormous opportunities for innovation and change as organizations reevaluate their business top-to-bottom.

## The Age of the Patient

The patient has left the doctor’s office and entered the boardroom, where their influence has revolutionized and upheaved nearly every aspect of operations, strategy, and technology for life sciences organizations. Patients not only have more access to information about their care and condition(s) but they’ve been empowered to take a more active role in their therapeutic treatment. As companies navigate this new power dynamic and undergo increasing scrutiny, engaging the patient through the most effective, accessible, and relevant channels has never been so important.

### Patient-Centricity



**In a survey of life sciences companies, 89% of United States cross-functional teams contributed to implementing or promoting patient-centric initiatives.<sup>1</sup>**

Where patient-centricity seemed more like a marketing buzzword less than a decade ago, it’s now a mentality and capability that is being (and must be) embedded across almost every functional area, from research and development to legal affairs and more. Communicating and leveraging these capabilities externally will be increasingly important as patients and regulators demand patient-centricity as a means for improving outcomes.

### Engaging the Provider



**55% of U.S. patients believe that solutions for today’s health care challenges will come from health care providers, i.e. doctors or nurses.<sup>5</sup>**

The relationship between providers and drug manufacturers continues to evolve as physicians are looking for education on the therapeutic and financial benefits for their patients. Even as the industry continues to get closer to the patient, the provider will be the most effective influencer with the most direct route to the patient.

### Beyond-The-Pill



**In just 2017, the mobile health market will account for \$23 billion in the global economy.<sup>2</sup>**

Maximizing therapeutic value isn’t just about the efficacy of the drug anymore, it’s about the entire experience. Leveraging mobile health capabilities (as doctors/caregivers have) will allow pharma to demonstrate “beyond-the-pill” value and educate patients through a more accessible and personal channel.

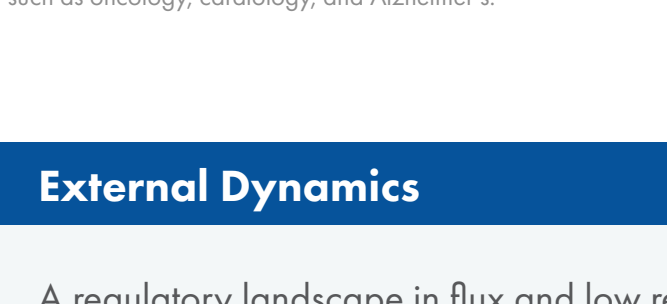
### Patient Pricing Pressures



**Only 9% of U.S. consumers believe pharmaceutical and biotech companies put patients over profits.<sup>4</sup>**

The United States pharmaceutical industry has seemingly entered a nadir of trust with the American patient. Regaining that trust will require a delicate balance of educating patients on the development, manufacturing, and distribution process while also innovating drug discovery and creating value beyond the treatment.

## Growing and Graying Populations



**The global total of people aged 60 or older is expected to grow by more than 500 million by 2030, to 1.4 billion people.<sup>3</sup>**

The life sciences industry must be prepared to address the needs of a “growing and graying” portion of the world’s population through targeted innovations in therapeutic treatments for areas such as oncology, cardiology, and Alzheimer’s.

## External Dynamics

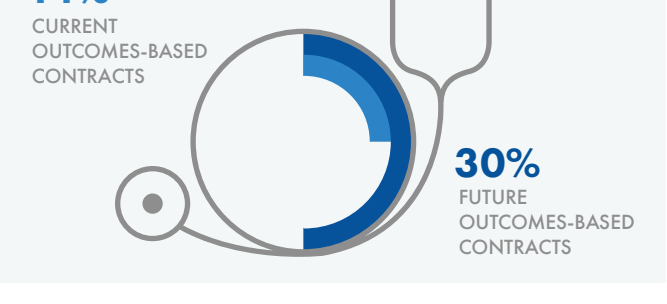
A regulatory landscape in flux and low returns on previous M&A activity has created an air of uncertainty and caution in the life sciences industry. Looking forward, companies that strategically focus on and grow their core strengths will be able to more effectively communicate their value and regain the value of M&A through a more targeted approach.

### Political Pricing Pressures



Surprising to few is the fact that everyone – regulators, the public, the media, etc. – are scrutinizing drug pricing with increasing vigilance. Educating regulators and the public on the financial cost of innovation for each drug and the associated costs for distribution will continue to be a key strategic priority.

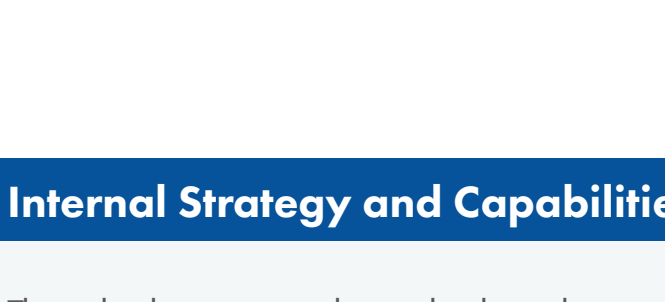
### Drug Approvals



**In 2016, the FDA approved 21 new drugs – a 46% decline compared to 2015’s 45 new drug approvals.<sup>8</sup>**

As the FDA becomes more scrutinous in their approval process and the total cost for bringing a single drug to market skyrockets, pharma will weigh the accompanying risks of drug development from a more cautious perspective. That in mind, orphan drugs will continue to be a more attractive investment due to the associated regulatory incentives.

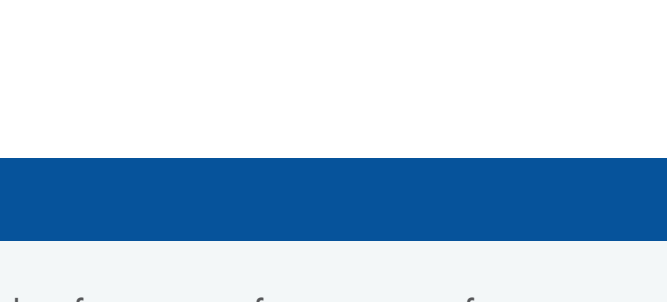
### Regulatory Uncertainty



**A January 2017 press conference held by President Trump regarding drug pricing coincided with a \$24.6 billion decrease in market value for the 9 largest pharmaceutical companies on the S&P 500.<sup>7</sup>**

The early days of the Trump administration have had significant effects on the life sciences industry while still leaving a good deal of uncertainty as to how the new administration (and other political shifts, e.g. Brexit) will impact the industry in a lasting way. Understanding the small but substantial difference between uncertainty and risk is especially key. Organizations that focus more on managing risk (something that they can control) will allow them to better manage the uncertainty (something they can’t control).

### Value-Based Care



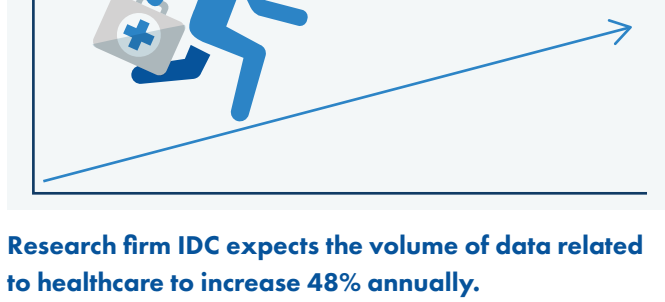
**14% of payers currently have outcomes-based contracts with manufacturers for a drug’s performance with an additional 30% planning to implement outcomes-based contracts within the next 12 months.<sup>9</sup>**

The perfect trifecta of pharma influencers – patients, regulators, and payers – continue to push manufacturers towards value-based (or outcomes-based) contracts. Developing and measuring those outcomes, however, is nebulous at best for many therapeutic areas. Gaining agreement among all stakeholders on how to measure therapeutic value also brings challenges. Exploring unique partnerships and capabilities for patient engagement will give manufacturers greater and more immediate access to the necessary data to inform contracting decisions.

## Internal Strategy and Capabilities

Though almost everything else has changed, the last few years of seismic transformation in the industry haven’t minimized the continuous pressures on life sciences organizations to innovate and grow. Companies are addressing these pressures with the familiar tools and strategies, namely mergers, acquisitions, outsourcing, and advanced technological/digital capabilities. What has changed, however, is the way in which organizations are leveraging these tools.

### M&A Value Inflation



**In 2016, the median value of a pharmaceutical acquisition was 39 times the revenue of the acquired company, compared with 2015’s 19 times.<sup>10</sup>**

With the cost of M&A rising and the value inflating, life sciences companies are naturally seeking more targeted deals. To that end, more organizations are pursuing an acquisition strategy for vertical growth – acquiring companies that grow capabilities in a specific therapeutic area to better serve those patient populations.

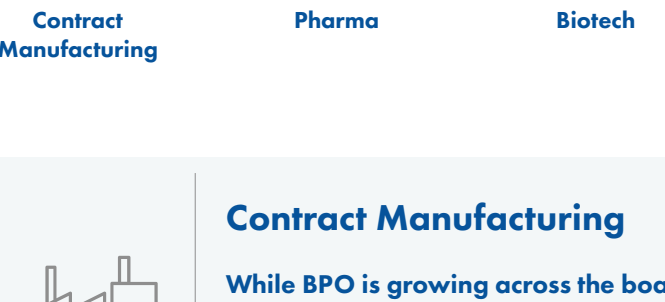
### Growth in Outsourcing



**The business process outsourcing (BPO) market in the life sciences industry is estimated to reach \$424 billion by 2024.<sup>11</sup>**

For decades, outsourcing of certain business processes has been a staple of drug manufacturers as a means of controlling costs and maximizing efficiency. Looking forward, as margin pressures mount and operations continue to spread across the globe, opportunities to outsource even more functional areas (e.g., regulatory affairs, sales, marketing, etc.) will allow companies to decrease overhead and focus on operational strategy.

## Weathering the Data Tsunami



**Research firm IDC expects the volume of data related to healthcare to increase 48% annually.**

As artificial intelligence, the Internet of Things, and smart machines are created and used with increasing frequency, data volume will only exponentially increase while data inputs skyrocket. Creating scalable systems and analytics capabilities is a strategic imperative for life sciences organizations to not only manage but optimize the “data tsunami.”

## Key Sector Deep Dive

Key sectors of the life sciences industry face category-specific opportunities and drivers that will invariably shape the coming years for their business. As we look to the remainder of 2017 and beyond, below are just a few examples of the opportunities available to these industry segments.

Contract Manufacturing	Pharma	Biotech	Generics	Medical Device	Wholesale Distribution
<p><b>Contract Manufacturing</b></p> <p><b>While BPO is growing across the board, the contract manufacturing market specifically is predicted to grow to \$124 billion in 2027.<sup>12</sup></b></p> <p>As increasingly significant links in the value chain, CMO’s should focus on maintaining compliant systems and processes that allow for integration into a client organization’s existing quality and regulatory operations.</p>	<p><b>Pharma</b></p> <p><b>According to a 2016 report by the International Trade Administration, only 2 of 10 medicines on average produce ROI over R&amp;D costs for pharmaceutical manufacturers.</b></p> <p>Pharma manufacturers have long understood the high-risk and high-cost implications of in-house drug development. But ever-growing margin pressures and increased financial scrutiny are forcing manufacturers to innovate and reconceptualize even the most elemental business functions, requiring new technologies and business partnerships to increase the speed to market while still ensuring patient safety.</p>	<p><b>Biotech</b></p> <p><b>Tissue engineering and regeneration accounted for 30% of revenue in the biotech market in 2015.<sup>13</sup></b></p> <p>With chronic and age-related diseases on the rise, the investment of biotech companies on the diagnostic capabilities for these conditions is already paying off. As organizations look forward, similar investments in the diagnostics and analytics will allow for further growth in specific therapeutic areas.</p>	<p><b>Generics</b></p> <p><b>The global generics market is expected to grow at a compound annual growth rate of over 10% from 2016-2020.<sup>14</sup></b></p> <p>To sustain their current growth trajectory in the future, generics companies should start to consider requirements for entering new markets, such as biosimilars. Investing now in the necessary capabilities for the more complex regulatory and production process of biosimilars will allow generics companies to capitalize more efficiently.</p>	<p><b>Medical Device</b></p> <p><b>Estimates forecast the global implantable medical devices market growing to \$54.28 billion by 2025.<sup>15</sup></b></p> <p>Implantable devices are advancing to address conditions where pharmacological treatment was previously underwhelming (e.g. blindness, deafness, degenerative diseases, etc.), which has contributed to growth. An aging population dependent on implantable medical devices will also spur growth and give medical device manufacturers a strategic focus.</p>	<p><b>Wholesale Distribution</b></p> <p><b>Manufacturers are preparing for the November 2017 Drug Supply Chain Security Act deadline.</b></p> <p>As manufacturers prepare to meet regulatory requirements around serialization, the role of wholesale distributors as key components for end-to-end visibility will require systems/data integration and a more collaborative relationship.</p>

**About the Author**

Janel Firestein leads Clarkston Consulting’s life sciences practice, helping senior leadership in the pharmaceutical, medical device, and biotechnology industries address industry trends and challenges. She’s a frequent speaker and recognized expert in not only the life sciences industry but business areas such as supply chain, quality operations, regulatory strategy and compliance, information technology, and change management.

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For detailed information about how we work with life sciences companies, visit our website: [www.clarkstonconsulting.com](http://www.clarkstonconsulting.com)