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Ten Critical Shifts Reshaping Drug Development And Commercialization In 2019

A Snapshot Of What's-Next Insights To Help Biopharma Leaders Navigate Challenges And Capitalize On The Opportunities Ahead

In 2019, the character and cadence of health care will demand greater depths of data savvy and ever-faster decision reflexes from health care leaders. This axiom will apply whether the conversation is about digitally empowered patients who expect to be rewarded for sharing their experiences with drug developers, or the ripple effects of consolidation among payers and pharmacy benefit managers, or the impact of regulatory and business reforms that are poised to make China a global pharmaceutical powerhouse.

“Our industry is overwhelmed with data, and the possibilities for action and investment are enormous, but there’s little clarity around how to move forward,” says Leigh Householder, Syneos Health’s executive vice president for insights and innovations. “Even when armed with every imaginable number, too many health care leaders are struggling to gain strategic traction. What teams throughout the industry need are decision-driving insights.”

To address this need, Syneos Health engaged more than 200 internal subject matter experts working on the front lines of drug development and commercialization around the world to identify drivers of change in their sector and calibrate the impact over the next six to 12 months. Among the 10 predominant trends uncovered, there is an urgent need for:

- **Relearning Launch:** Across the biopharma industry, the odds of developing an asset, getting it approved and successfully bringing it to market are about the same as winning a single number in roulette: 3%. Many innovators are approaching launch with one foot on the brake and one foot on the gas. Yet, a fainthearted stance can be hazardous. By pushing investment later and later in the launch cycle, companies are missing out on the value creation cascade that typically starts three years before launch and increases significantly one year out. Comparing the investments of 19 biopharmaceutical companies launching their first products, Syneos Health found that no company spending less than 75% of its launch-year-forecasted revenue in the first 12 months of launch

achieved commercial success. The solution to many challenges lies in tighter, agile coordination. This year, we’ll see more cases where medical affairs teams will fuel a feedback loop from providers and payers to aggregate and understand what evidence is most needed across and within regions. Some of that evidence will be advanced at a national or global level and some will be created within region, through real-world trials that leverage nimble techniques like retrospective chart review and virtual staff.

- **Accelerating Evidence:** In the US, the 21st Century Cures Act codified a commitment to change by emphasizing the patient’s perspective on drug development and empowering innovators to experiment with trial design and outcomes assessment. Europe is moving in the same direction. China, meanwhile, has adopted a mesh of incentives and penalties to speed clinical testing at home and abroad. The goal is to achieve parity with leaders in other regions, both in drug innovation and market access. In all major markets, we’ll see greater focus on what product differentiation looks like in real-world environments. Increasingly, submissions for the approval of innovative drugs and devices will include real-world evidence drawn from clinical data, claims data and patient-generated data that may emerge from novel sources such as social media. To build those packages, more clinical teams will be collecting real-world data and evidence in very early stages of trials, while making broader use of “pragmatic” trial designs.

- **Search for the Right Patient:** Where once innovators of drugs, devices or digital therapeutics might have dreamed of owning an entire patient category, more industry leaders in 2019 will aim for 100% of patients in a much smaller population where treatment can make the biggest difference. To get there, innovators are testing therapeutics not just against well-known levers such as biomarkers and demographics, but also against new ones like patient behavior tracked with diaries and wearable devices. With an eye to differentiation and sub-segmentation, smart investment this year will flow to subset research that competitors just haven’t analyzed yet. In

addition to building patient journey maps providing a nuanced real-life view based on patient-relevant claims code and Internet search data, leaders will leverage de-identified clinical and genomic data to estimate the number of patients who match specific criteria and see a comprehensive aggregated picture of the cohort.

- **Radical Reorganization:** At a moment when risk and uncertainty are permanent guests at the table, life sciences leaders need more flexibility than they can obtain through traditional financial levers such as slashing staff or throttling R&D. To protect their pipelines, they must replace costly infrastructure with “rented” capabilities of more adaptable partners. This year will see a significant shift to horizontal contracting, transferring critical parts of the commercial organization from an ownership model to a rental model. Health care innovators will hire more talent from outside the industry, whether from Google or Walmart. These and related shifts will lead to more rapid cycling of innovation and optimization, with biopharma companies learning from their customers and making changes in evidence collection, messaging and service provision.

Other shifts and underlying dynamics that will shape biopharmaceutical decision-making in 2019 identified in the *Health Trend Ten* eBook from Syneos Health include:

- **Rewired HCP:** Today, two thirds of US physicians report that they’re burned out, depressed or both. This job dissatisfaction doesn’t hurt just professionals – increasingly, it’s impacting their patient relationships as well. Physicians are working with less control, greater financial and time pressure, torrents of data that can be as much a burden as a blessing and increasing mental health challenges.

- **Relieving Burden:** At a time when the weight of work is piling up on critical stakeholders, old and new players are stepping in with strategies and services that reduce friction, complexity and inconvenience for doctors, researchers, patients and harried administrators. For example, to serve practices in a resource-starved, formulary-first era, field teams are spending more time on patient and practice support.

- **System of One:** Care is becoming more transient, opportunistic and data-connected as it shifts from hospitals to homes, local pharmacies and even onto mobile phones. This ability to leverage technology to reach patients has the ability to impact conversations about care within the retail and primary care environment, clinical trial recruitment and collection of real-world evidence.

- **Value Puzzle:** Innovation, politics and data have reenergized debates about value, with people, payers and advocates all asking: is it worth it and who should pay? We may also soon see frank discussions on



pricing coming to the point of care. Electronic health records, HSA-style insurance plans and state and national laws are making doctors and patients more aware of the real costs of medications and procedures.

- **New Top Talent:** Massive shifts in the expectations of customers and the reality of health care are driving demand for talent ready to excel in this new era. Employers are on a quest to identify and attract the most versatile, skillful, and regional- or global-savvy workforce – often in places you wouldn’t expect. There are also shifting expectations on talent – from clinical site managers and educators to marketers and sales reps – to work as comfortably with data as they can perform real-life engagements.

- **Demand for Decision-Driving Insights:** Life sciences leaders are managing pressure on time and resources at a moment when the velocity of change and opportunity is faster than ever. There is a need to quickly create business cases, advance institutional data fluency and infuse behavioral science into decision-making – all to forge meaningful change opportunities and sustain momentum to execute on the plan.

Download the [Health Trend Ten eBook](http://www.trends.health) (www.trends.health), a compendium of trend forecasts and analyses to help industry leaders anticipate changes on the near horizon. The book includes 10 macro trends and 40 themes for 2019 and 10 worksheets to help evolve and transform your 2019 planning. A companion podcast series is also available [here](http://www.trends.health) (www.trends.health).