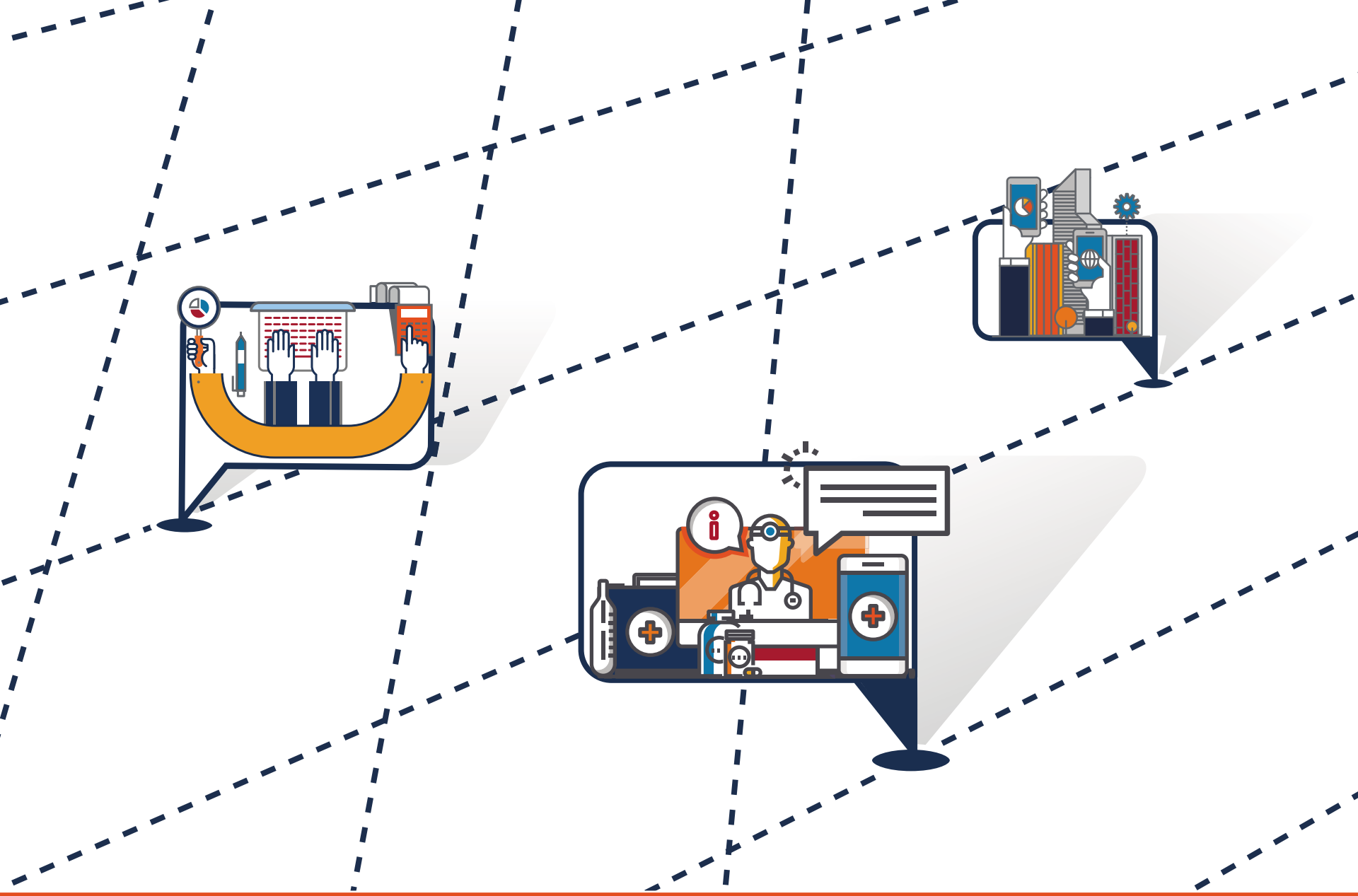


Syneos Health

2019 HEALTH TREND TEN

Your 2019 Health Trend Ten

Disrupted. And disrupting.

The year of change, innovation and challenge ahead.

We enter this new year inspired by the power of science, the persistence of patients and the success of survivors. New choices from mutation-derived targeted treatments to digital therapeutics have captured the global imagination. The impact of biomedical innovations has ushered in what scientists call an Age Wave. The number of people age 65 or older increased tenfold in the last one hundred years and older people are living longer and in better health than ever before.

We live in truly incredible times.

As remarkable as this new era is, it also challenges us as an industry. We're racing to radically retool our organizations to work in more agile ways. We're creating powerful new evidence to answer important questions about the impact treatments have in the complex real world. And we're making everything—every communication, every treatment, every label—infinitely more personal and actionable for people and professionals.

And we're doing it all at break-neck speed.

Our healthcare provider partners, too, are facing new burdens and stresses from the very personal impact of mental health issues to the systemic challenge of navigating an increasingly complex reimbursement environment. As an industry, we're standing up new talent to support those professionals in right-now relevant ways while changing our processes to elevate and amplify the patient voices we're all guided by.

In this fast-changing landscape, it's no surprise that life science leaders need new levels of decision-driving insight from their partners, ideas and business cases that drive action.

In this report, we sought to dive deep into all the aspects of change 2019 has in store. We're asking new questions with the goal of co-creating new solutions that help us all deliver on the possibilities of science.

Alistair Macdonald
Chief Executive Officer

Owner's Manual

Our 2019 Health Trend Ten book is packed with inspiration for the year ahead.

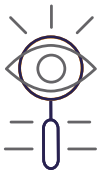
10 trends

40 break-out features

94 illustrations and charts

1 incredible source for what's-next thinking

Here's how it works:



SCAN

Use the Table of Contents to quickly scan the Top 10 macro trends changing our industry and opportunity. Flag, highlight or circle the ones of most interest to your work.

EXPLORE

Dive into each of your highlighted trends. Use the features and callouts to understand different aspects of each trend. Dog-ear your favorite pages and underline the most relevant ideas.

BRAINSTORM

Use the worksheets in each trend to dive deep into key questions about how you might learn from that trend to evolve or even transform your approach to engaging stakeholders in 2019.

KEEP

Find the poster in each of your favorite sections and tear it out. Hang it in your workspace, tuck it in a notebook or send it to a friend to keep that trend top of mind throughout 2019.

Table of Contents

RADICAL RE-ORGS

Internal change is happening fast in 2019. It's driven by a basic economic need to flex the cost structure. But, more importantly, it's fueled by a new commitment to mix talent, encourage collaboration and always innovate from the perspective of the patient.

Radical Re-Orgs | Dynamics

Variabilization of Costs

To protect their pipelines, life science leaders have to replace costly infrastructure with more adaptable partners. In 2019, look for a significant shift to horizontal contracting.

(READ MORE ON PAGE 8)

Always-On Commercial Lens

To continue to design the right solutions and evidence for patients, payers and providers, clinical and commercial are partnering in new ways. They're working to define the economic impact and burden relief of new and established treatments.

(READ MORE ON PAGE 9)

Leapfrogging Change

Companies are re-centering hiring on domain expertise as opposed to category expertise, with GSK hiring marketing leaders from Google and Akili building from the ground up with Apple alums.

(READ MORE ON PAGE 10)

Patient-Centric Trials

Patient centricity is making a comeback. In 2019, the most patient-centric organizations will have one thing in common: senior management endorsement that includes specific measurable goals.

(READ MORE ON PAGE 11)


RADICAL
RE-ORGS

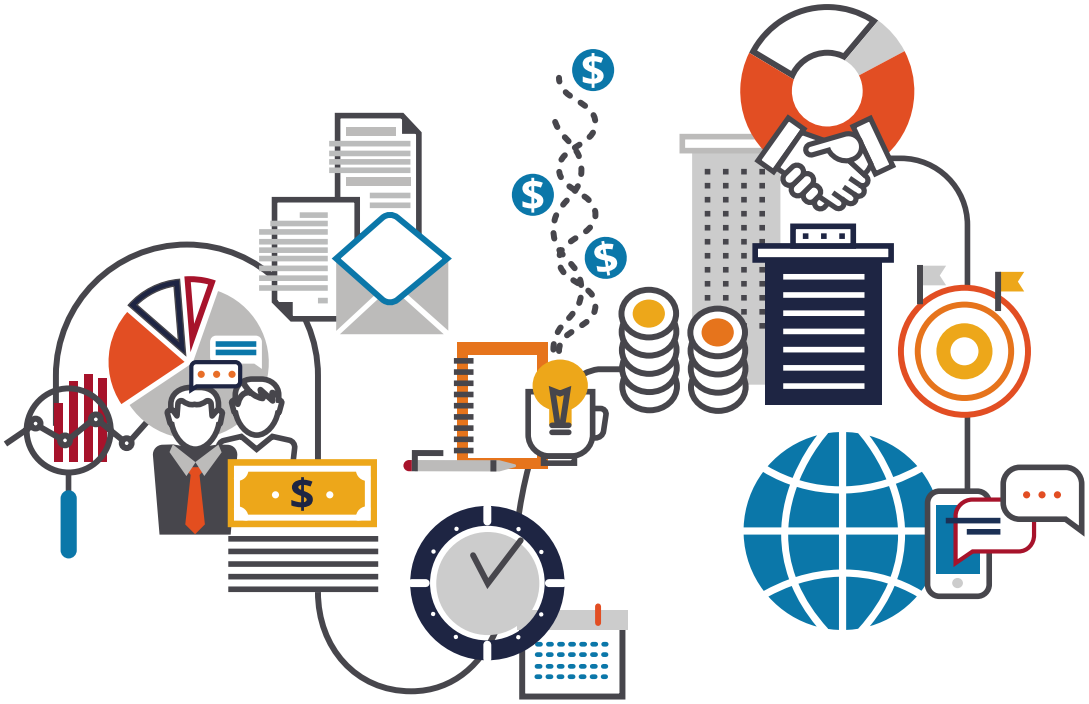
Variabilization of Costs

Risk and uncertainty are greater than they've ever been.

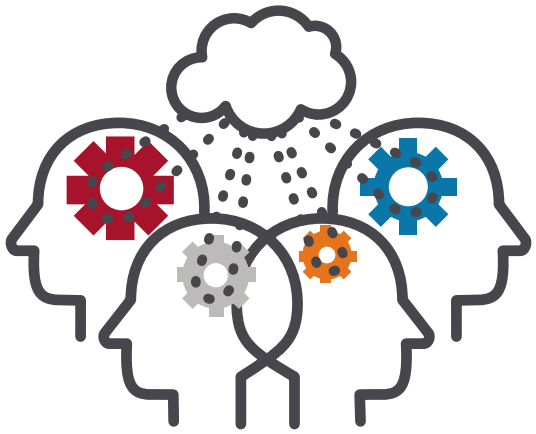
Managed-markets decisions increasingly drive launch success. The experiences of a few create the perspectives of many. Regulations and legislation change at the whim of a tweet.

In this climate, life science leaders need flexibility. Traditionally the only financial levers they had were cutting staff or limiting research and development. To protect their pipelines, they have to replace costly infrastructure with more adaptable partners.

In 2019, look for a significant shift to horizontal contracting. This approach will move critical parts of the commercial organization from an ownership model to a rental model. Importantly, it will also drive more integration, aligning strategy and metrics across all aspects of the commercial team.



Pharma Looks to Partners for Flexibility



According to a recent survey, life science leaders are increasingly looking to outsourcing to fuel commercial growth. Here's why:

60%
of respondents said "greater flexibility of commercial scale" is the no. 1 benefit to commercial outsourcing

49%
said that the ability to tap into proven external technological solutions is a key driver for their organizations

40%
indicated that they use outsourcing to fill skill gaps within their own organizations[38]

Always-On Commercial Lens

Multidisciplinary collaborations are driving growth in 2019.

Commercial teams are entering strategic discussions earlier, often brought in by clinical partners to help define the most valuable evidence to collect. That's driving new, frank conversations about product development, starting from a new competitive reality: Not every product has a market and not every product has the market that inventers might initially think.

To continue to design the right solutions and evidence for patients, payers and providers, corporate leaders are defining new metrics that further connect efforts across the clinical to commercial landscape. These impact-driven lag goals include measures like acceleration, excellence and reinvention.

Commercial is learning deeper science and more technical complexity from clinical. Clinical is borrowing proven capabilities in patient/advocate engagement and behavioral science from commercial. The two teams are partnering in new ways to define the economic impact and burden relief of new and established treatments.

These collaborations are creating new training grounds. Once top talent would be expected to work across a small number of commercial disciplines to prepare for a leadership role; today, that same high-potential individual will expect a tour of roles in clinical and commercial, as well as externships and embedded opportunities in key partners and even customers.

2019 Buzz Word: Optionality

Until recently, companies had essentially three options for an asset, all with varying degrees of control:

Sell or license	Partner or co-promote	Commercialize alone
retain zero percent control	retain approximately 50 percent control	retain 100 percent control

Each of those options also includes a degree of burden, with self-commercialization presenting the largest burden to a company.

Optionality is about creating a fourth option, not just for what you do, but how you do it.

The fourth option allows a company to pursue commercialization with an outsource partner, so the infrastructure and build burden is significantly reduced, but 100 percent of control is retained. A company doesn't lose any of the original options and can actually increase the value associated with those options by getting further along the path to commercialization.

Leapfrogging Change

The way healthcare innovators are working today is more rapid and real time.

They're looking to master consumer-packaged goods best practices by infusing agility and responsiveness into every strategy. The result is more rapid cycling of innovation and optimization. They're learning quickly from customers and, in response, changing evidence collection, messaging and service.

Increasingly, the companies that are breaking out are selecting talent from well outside the industry—whether that's GSK hiring marketing leaders from Google or Akili building from the ground up with Apple alums. Those outside hires demand new kinds of integration that help healthcare experts and technology veterans productively challenge one another and get to new common ground.

Part of this change is also re-centering hiring on domain expertise as opposed to category expertise. Look for more marketing suites to hire pure-play marketing experts, regardless of healthcare experience, and field teams to seek out incentive veterans and proven sales leadership. This shift will rapidly increase the sophistication of commercial healthcare tactics, but it will also challenge the talent pipeline that has long fueled the sector's growth.

Big Pharma Increasingly Interested in Agile

Large life sciences companies understand the speed of change and increasingly want to work just as fast. As they evolve their internal organizations to work at speed and scale, they're increasingly engaging start-ups to fast-start change via venture capital, licensing and incubation.

For example, the industry has not successfully developed a new generation of antibiotics. So, Novo Holdings — which has big stakes in Danish drugmaker Novo Nordisk — recently launched a $165 million venture fund focused on new approaches to combatting superbugs that are resistant to modern antibiotics. That access to external innovation is becoming a critical part of the pipeline, as recent research shows that 63 percent of the novel approved drugs in the last five years came from small innovators.[27]

These fast-moving collaboratives aren't just science, they're also service. Merck and Amazon recently partnered to launch a voice navigation challenge for healthcare. Dubbed the Alexa Diabetes Challenge, the contest aimed to incent upstarts and individual developers to create apps that harness Amazon Alexa's voice-enabled technologies, particularly for patients recently diagnosed with type 2 diabetes. The winner, Sugarpod by Wellpepper, is a multimodal care plan that lets users select their own healthcare tasks and prompts, and reminds them via voice and text interfaces.

Patient-Centric Trials

Patient centricity was once a phrase that received the same cynical sigh as a mention of QR codes.

But patient-trials are in the middle of authentic comebacks. Increasingly, clinical teams are integrating the patient voice into every aspect of trial development. They're developing frameworks that ensure consistency across large originations, investing significant resources, hiring dedicated specialists, and tackling barriers in focus and communications.

In 2019, the most patient-centric organizations will have one simple thing in common: senior management endorsement that includes specific measurable goals to work toward together. From there, dedicated teams will approach process and perspective challenges. They'll diagnose obstacles to change and map specific plans to overcome them, including policies, governance and frameworks. In tandem, they'll tackle culture change, giving people permission and tools to work in new ways.

Leaders at Pfizer defined three simple questions to center design on the needs of patients and give each of their teams a true north for patient centricity:

1. **What do we know from the patients' perspective about our development plan or trial?**
2. **How are we incorporating patient knowledge and experience into our development plan or trial?**
3. **What's the value to patients for our project?**

How Novartis Operationalized Patient-Centered Innovation

In 2015, Novartis made a bold declaration of what patients should expect from the company, in areas ranging from clinical trials to access to medicines. To bring that vision to life, Novartis has continued to make specific, tactical moves to bring the patient voice into every aspect of drug development.

One example of a process change is in the clinical development plan. It's put together after the drug is past proof of concept, and it aligns the frontline team and senior leadership around every aspect of how they'll develop the product going forward. Every clinical trial team at Novartis also has to complete a patient engagement plan as part of that overall document.

An internal patient-engagement champions network focuses on culture change. They're clinicians in every therapeutic area who spend a minimum of 10 percent of their time better understanding the tools of patient engagement and how they can drive change.

Another culture shift is actively creating empathy for real-life experience. In preparation for the launch of a drug for chronic heart failure, the team learned the patient journey as a team simulation. Some people were whisked off to an ER. Others wore heavy vests to feel how hard it would be to breathe or sorted up to 20 medicines to make a personal plan. Some were told they had died.[1]

Future Ready

Questions and Discussion for Radical Re-Orgs

Is our outsourced contracting horizontal and strategic? Can we find new ways to work with partners to deliver on overall impact vs. filling individual roles?

When is our commercial organization engaged by clinical teams? How can we more effectively break down silos to ensure we're identifying the right markets, right questions, and right evidence?

How are we evolving the skills of our people? Can we work in sprints or leverage design thinking? What more do our teams need to leap ahead?

Are the processes in place to ensure the patient voice is included in all of our trial design? What governance or systems would help our teams better engage patients and advocates?

ACCELERATING EVIDENCE

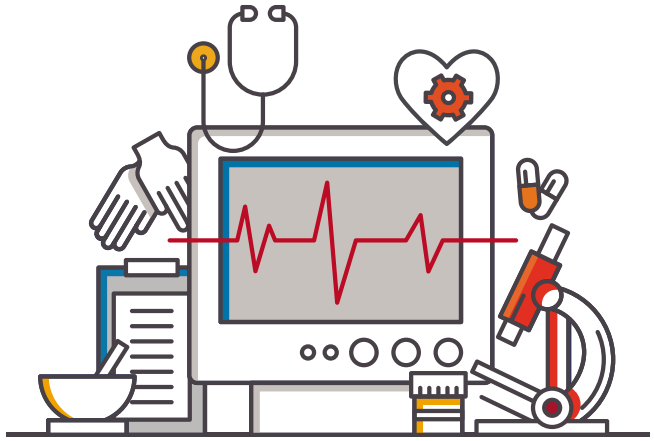
Regulators around the world are creating policies and collaborations to test novel science and technology faster, understand the real-world impact of treatment and seamlessly learn across geographies.

Accelerating Evidence | Dynamics

Global Commitment to Speed

China is simultaneously working to combat fraud and accelerate development, and its efforts may soon make the country a global leader in the efficient collection and application of real-world data.

(READ MORE ON PAGE 16)



Breaking the Sequence

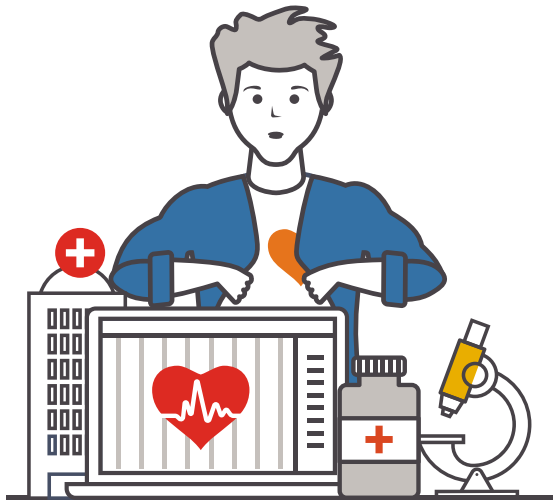
With global regulatory criteria evening out and new digital interventions rising, more studies are using parallel paths of inquiry to introduce new therapies faster.

(READ MORE ON PAGE 17)

Real-World Requirement

In 2019, expect pragmatic trials, basket trials and competitive analysis to bring forward new decision-driving criteria, with a focus on understanding what works and scaling that knowledge across networks.

(READ MORE ON PAGE 18)



Rise of the Pragmatic Clinical Trial

The reform environment, with its emphasis on real-world evidence, is set to favor PCTs. Pragmatic clinical trials (PCTs) happen in health systems with their existing patient population, instead of at clinical trial sites with a carefully recruited cohort.

(READ MORE ON PAGE 19)

Global Commitment to Speed to Market

Around the world, governments are working to speed critical treatments to market in a complex environment where some of those innovations require new endpoints, approaches and questions.

In the U.S., the 21st Century Cures Act codified a growing commitment to change. The law built on the FDA's work to bring patient perspectives into the development of new treatments and cures, and gave healthcare innovators fresh abilities to modernize trial designs and outcomes assessments.

But it may be in China where the biggest changes are happening.

China is simultaneously working to combat fraud and accelerate development. With patients waiting as many as six years[8] to have access to treatments already approved in other markets, the government knew it needed to reform in a way that prioritized safety and speed.

In late 2016, the Chinese government began cracking down on fraudulent behavior—specifically, companies submitting error-filled clinical trial data. The new rules promised more reviews of the data and penalties for false reporting. As soon as the change was announced, 60 submissions were withdrawn.

A year later, the government announced five changes set to radically transform "the drug lag." The most critical: accepting data from clinical trials run outside of the country to attain conditional approvals. Early conditional approvals in HPV, oncology and cardiology came quickly—within months or even weeks of that new regulation.

For multinationals, that shifts the burden of activity from running logistically difficult clinical trials in China to preparing for rapid commercialization, real-world evidence collection and post-marketing surveillance.

Looking out on the two-plus-year time horizon, that shift may well make China a global leader in the efficient collection and application of real-world data.

Three Ways the 21st Century Cures Act Accelerated the Drug/Device Approval Process in the U.S.

1. Allowing real-world evidence and data summaries to replace traditional clinical trials as criteria for approval when investigating new uses for existing drugs
2. Creating a limited population approval process for novel antibiotic protocols for severe and untreatable infections
3. Providing expedited approval paths for breakthrough medical technologies/ medical devices for patients with life-threatening diseases where limited treatment options are available

Breaking the Sequence

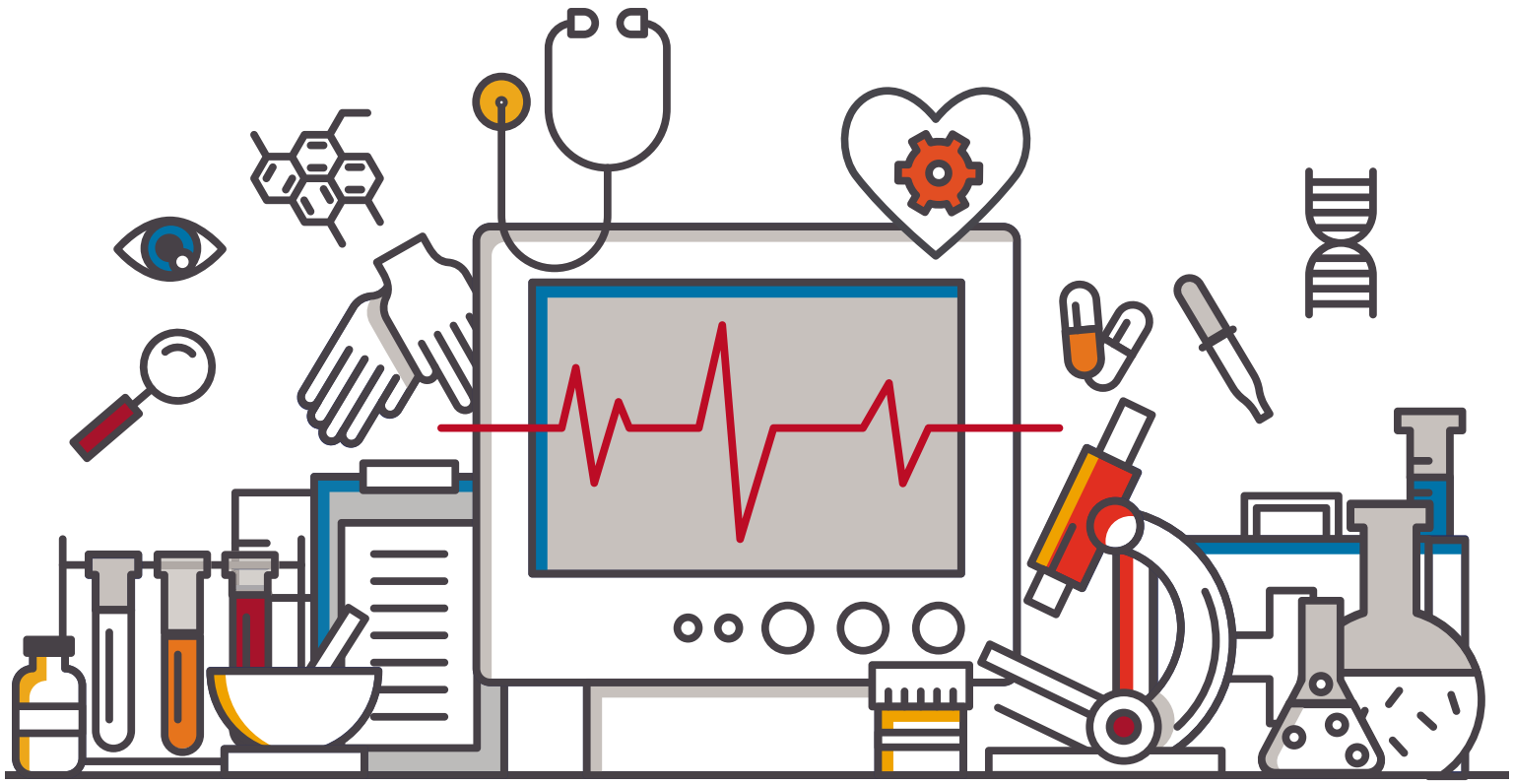
For medical devices, the environment is rapidly changing, in large part due to an evening out of global regulatory criteria, including more stringent regulations in Europe, a softening of the requirements in the U.S., and changes by the regulators in countries like China that are allowing for better, faster and higher standards of product approvals.

Previously, device manufacturers followed a sequential path of testing in the EU and the U.S., and later into AsiaPacific. But they're now experimenting with taking their highest-potential innovations through parallel trials in multiple regions to reduce time to impact.

Biosimilars are pushing on speed to study as well by compressing elements of trial timelines. In 2019, we expect continued transformation of the sequential approach, including overlapping phases, new submission strategies and alternate endpoints. Submission strategies might include moving clinical study reports (CSRs) up in the process, so that stakeholders can begin to see data when collection rates are at 80 percent to 90 percent of trial totals. New endpoints will offer the ability to see patient impact sooner, like adding pharmacodynamic (PD) measures to full clinical endpoints (e.g., 12-month progression-free survival).

Many studies are accelerated by virtual innovations, notably platforms like uMotif, on which a patient-centered interface encourages participants to log, on top of the data required by the study, as much real-world, personal data as they please. Because uMotif users benefit from their data submissions—they're able to track it and see what it's used for—they tend to provide more data more frequently. In turn, administrators get a density of data points that yields faster, shorter trials, cutting costs and getting therapies to market faster.

As companies continue to experiment with digital interventions – from ingestible sensors to simple companion apps – to help support their patients, we expect to see more parallel paths of inquiry that design clinical trial arms and late-phase research to better understand the value created by digitally enhanced support.



Real-World Requirement

Perhaps the biggest shift for 2019 and beyond is global focus on understanding what product differentiation looks like in real-world environments.

Pharmaceutical innovators and regulators alike are evolving their use of real-world data and evidence.

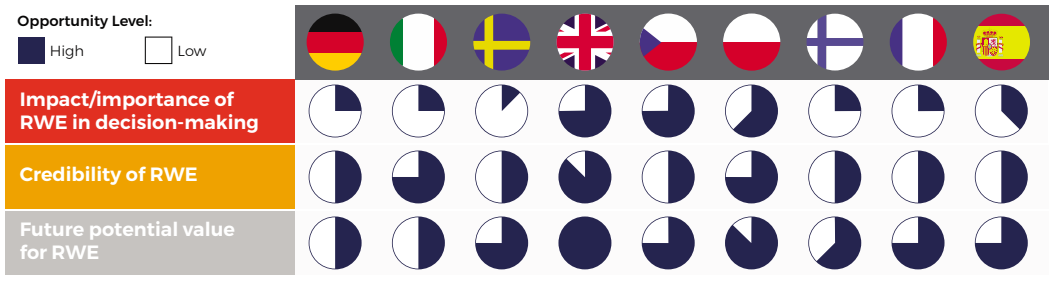
From the Baseline →	To Adding More Value	
Safety monitoring	Pharmacoeconomic models	Regulatory decision-making
Pharmacovigilance	Advanced disease understanding	Physician/system education

Increasingly, submissions for the approval of innovative drugs and devices will include real-world evidence submissions drawn from clinical data, claims data, patient-generated data and emerging data sources (like social media). The evidence will be used to demonstrate value beyond incremental benefit in patient lives.

To build those packages, clinical teams are already planning for – and often collecting – real-world data and evidence in very early stages of trials. What was once a "late phase" activity is quickly becoming an every-stage commitment.

Infrastructure built around the National Institutes of Health (NIH) Common Fund and the FDA's Sentinel Initiative, a post-market active safety surveillance system, suggests that the collection and interrogation of real-world evidence could even become a national imperative within the next four to five years. A comprehensive view established in one of those entities could create new standards, access and language around how to evaluate and integrate real-world evidence and data.

Policies for RWE Vary Significantly



Three scenarios of utilization

- Supplementary evaluation for market authorization
- Input into pharmacoeconomic analysis
- Re-assessment of relative effectiveness in conditional reimbursement schemes

EU countries are also implementing more stringent measures that will impact how value is assigned in the future

UNITED KINGDOM

- More rigorous evidence required to justify higher incremental cost effectiveness ratios
- Greater scrutiny of value delivered by drugs under Cancer Drugs Fund (CDF)

GERMANY

- Reimbursement restricted by patient sub-groups
- Companion diagnostics will be required for new drugs with "added benefit" rating

FRANCE

- Larger effect size being required for incremental added benefit rating (e.g., ASMR II vs ASMR III)
- Periodic benefit reassessment (every 5 years), but also on availability of new data (pharma initiated)

ITALY

- Early adopter of adaptive pathways
- Managed entry agreeements used broadly for addressing affordability issues – established registry infrastructure permits facile enforcement of both financial and outcomes-based MEAs

SPAIN

- Gradual adoption of cost-effectiveness in decision-making

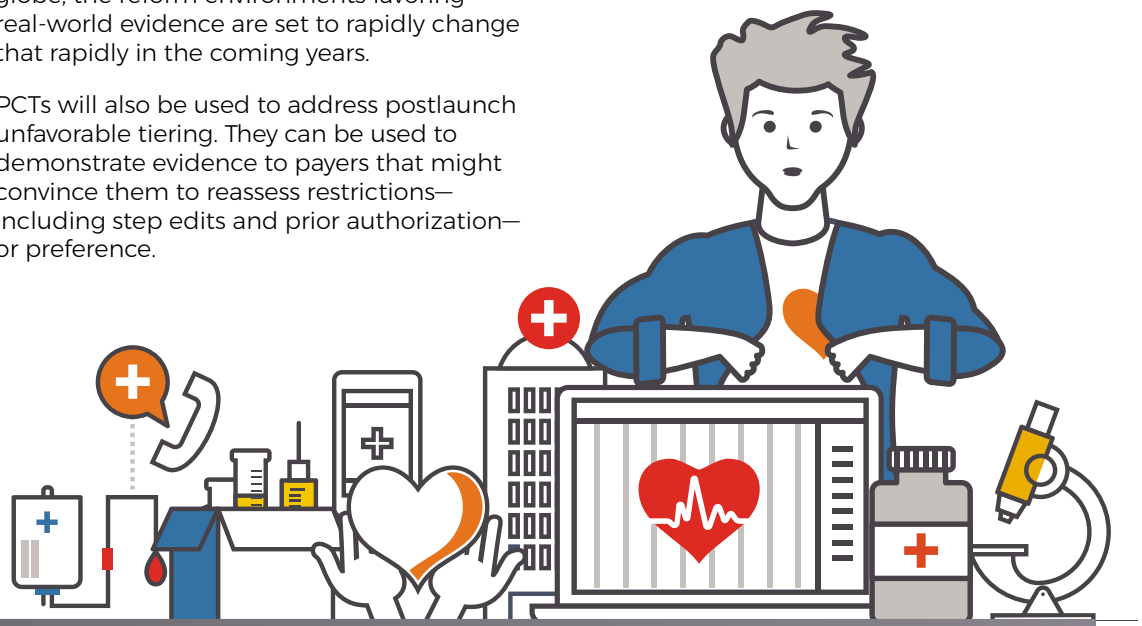
Rise of the Pragmatic Clinical Trial

With all these changes in competitive environments and evidence expectations, clinical and commercial teams are looking to different types of trial design that will help them earn and defend positions on formulary.

One approach we expect to have significant impact in the next 2-3 years is the pragmatic clinical trial (PCT). The PCT study design is the real-world analogue of the traditional randomized controlled trial (RCT). It combines elements of RCTs — treatment assigned by protocol, randomization, data collected on case report forms — with elements of noninterventional studies, like real-life practice conditions, more representative patient populations, non-intrusive forms of data collection, and active-comparator analyses. Importantly, they happen in the real world. So, things like co-morbid conditions, unsupervised adherence and patient-physician communication are more variable and uncontrolled.

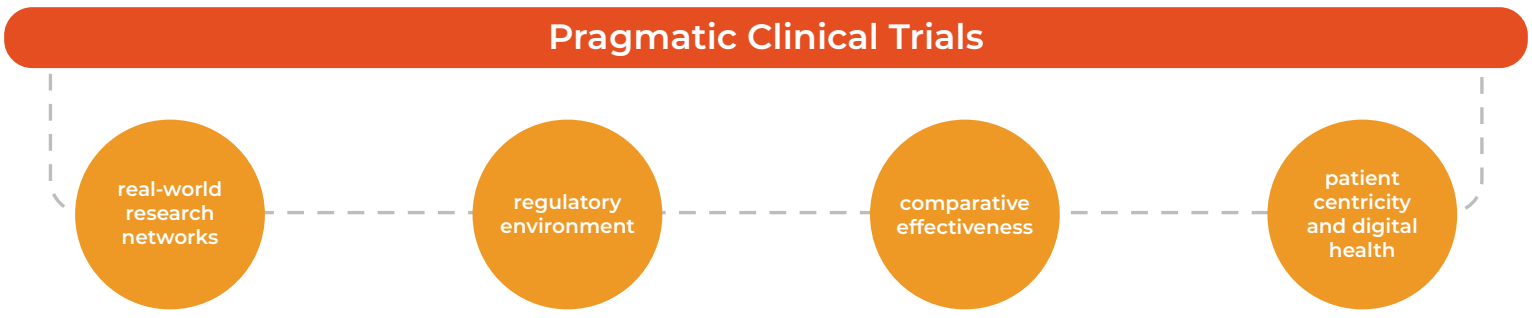
The PCT concept isn't new but manufacturers have not used it widely to date. Across the globe, the reform environments favoring real-world evidence are set to rapidly change that rapidly in the coming years.

PCTs will also be used to address postlaunch unfavorable tiering. They can be used to demonstrate evidence to payers that might convince them to reassess restrictions—including step edits and prior authorization—or preference.



New Partner: Real-World Research Networks

A broad set of market trends are driving the need for pragmatic clinical trials (PCT) and a new partner will make them easier and more efficient: real-world research networks. These networks, like National Patient-Centered Clinical Research Network (PCORnet), are consortiums of research sites that have made a commitment to real-world evidence collection and the always-on ability to conduct studies. They maintain a semi-permanent structure to fast-track everything from patient identification or enrollment to evidence collection.



Future Ready

Questions and Discussion for Accelerating Evidence

What do we need to do to get ready for the new speed to launch in China? Do we have the right methodology in place to develop valuable real-world evidence in the first years on market?

Could patient support and digital interventions support our drug's overall value proposition with payers and regulators? Do we have the right trial arms in place to create that evidence?

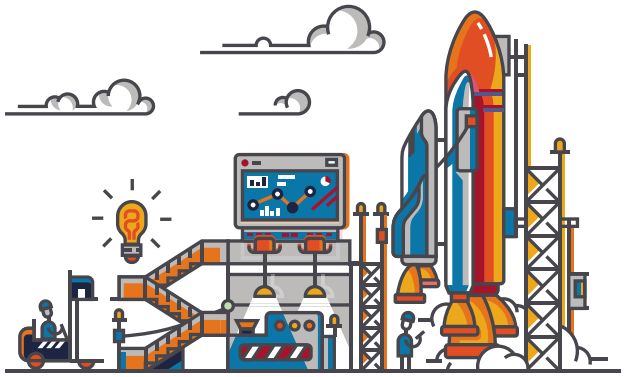
How powerful are the evidence packages we're putting together in this real-world era? What should we be asking in early phase to prepare for the new review landscape?

Do we have treatments on the market that are undervalued by payers? Is there new real-world evidence we could create to show where they should be advantaged in formularies?

RELEARNING LAUNCH

The need for bold launches is greater than ever; yet we enter 2019 constrained by resources and drive. As the science and economics grow more complex, teams need to prepare markets more comprehensively, redefining both metrics and regional relevance.

Relearning Launch | Dynamics



The Ultimate Gamble

At too many companies, maximizing the potential of launch is taking a strategic backseat to managing the possibility of risk. Being ready for those rare, high-potential launches will be the no. 1 imperative in biopharmaceutical innovation in 2019.

(READ MORE ON PAGE 24)

The Unprepared Market

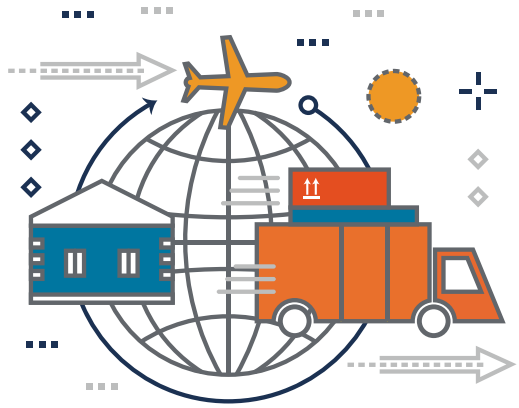
Due in part to the changing reimbursement landscape, many innovators are taking a newly conservative approach to launch. They're holding out hope that their molecule will change the market but holding back on investment to prepare that market.

(READ MORE ON PAGE 25)

Launching Regionally

To cater to increasingly regionalized authorities in the U.S. and elsewhere, pharmaceutical companies are creating their own responsive and right-sized regional teams.

(READ MORE ON PAGE 26)



Speed To Uptake—or Exit

Today, initial value has to be realized more quickly, and sustainability needs to be projectable over time. That's leading to new metrics that redefine performance, alongside new strategies, including exit planning.

(READ MORE ON PAGE 27)

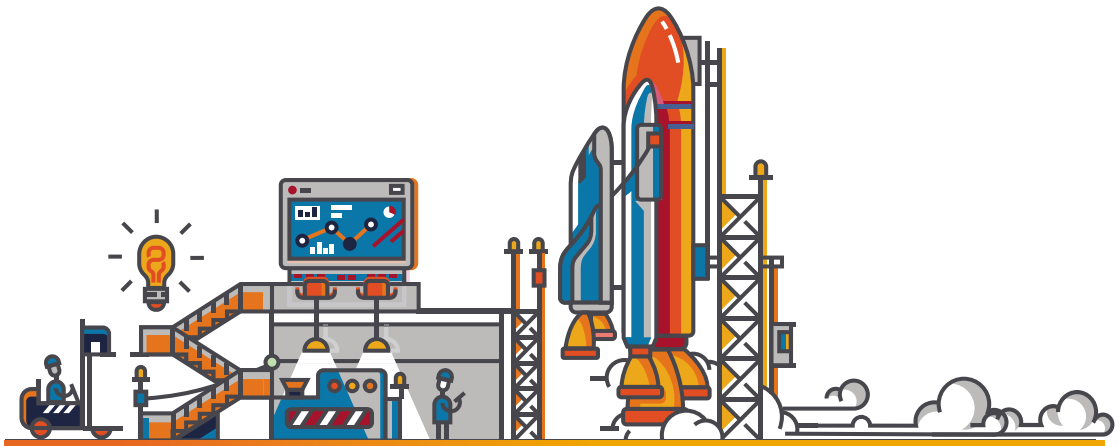

-RELEARNING-
---LAUNCH---

The Ultimate Gamble

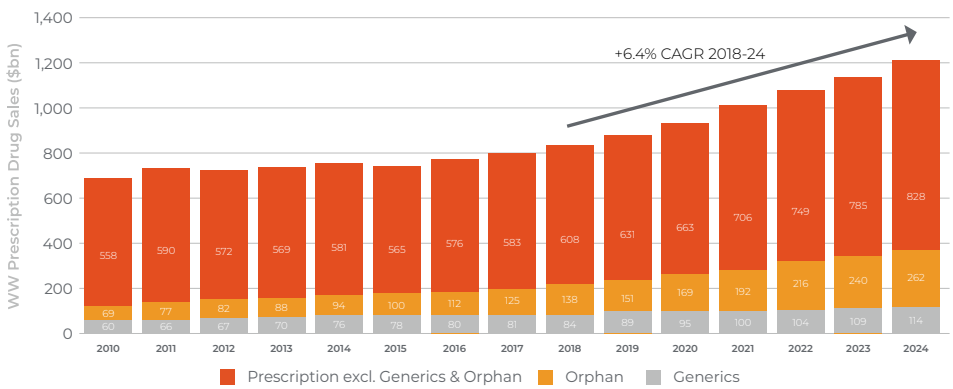
Across the biopharmaceutical industry, the likelihood of a new drug getting approved is hovering around 10 percent.

Of those drugs that are approved, roughly 30 percent will see commercial success. In other words, the odds of developing an asset, getting it approved and successfully bringing it to market viability are about the same as winning a single number in roulette: 3 percent.[40]

Being ready for those rare, high-potential launches is the no. 1 imperative in biopharmaceutical innovation today. But maximizing the potential of launch is increasingly taking a strategic backseat to managing the possibility of risk. Today, many leaders are shortchanging the impact of innovation at a moment that demands both advancing best practices and making calculated recalibrations.



Worldwide Total Prescription Drug Sales



Four specific market dynamics are changing the future of launch.

1. **A new cliff is looming:** Between 2018 and 2025, branded drugs worth more than $250 billion in sales will see their patents expire. This new cliff is driving SG&A pressure, corporate reorganizations and both high-expectation and highly conservative launches. Marketing and sales leaders are expected to fill the cliff gap with big returns on increasingly limited investments.

2. **The pipeline is booming:** Drug approvals are on a steady increase globally. Changes in approach in the U.S., EU and China are driving more parallel studies, more accelerated approvals and the accumulation of more real-world evidence for additional indications. The potential for overall growth is significant, but mismanaged launches could make that growth significantly uneven.[17]

3. **The science is increasingly more complex:** Many of the highest-potential innovations in the pipeline answer unmet needs in largely elusive disease states. Gene and cell therapies, novel approaches to rare disease and drug replacements, like digital therapies, are about to crowd the market, creating gaps in education for physician and payer alike.

4. **The economics are more complex, too:** Demonstrating an economic benefit is table stakes for today's launches. Regulators, payers and large organized customers expect to see an evidence package that includes impact on cost of illness, burden of illness, quality of life and impact on caretakers. Innovators are increasingly incorporating these health economics endpoints into Phase 2 trials, and throughout Phase 3 and real-world data collection.

The Unprepared Market

Many innovators are approaching launch with one foot on the brake and one foot on the gas.

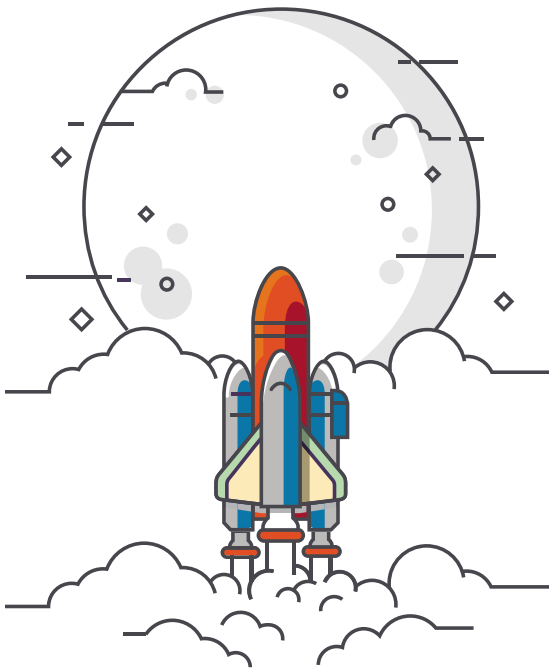
They're holding out hope that their molecule will change the market but holding back on investment to prepare that market. This newly conservative approach means that the runway from investment to approval can be as little as six months, a tiny window made even smaller by the outsized education demands of now-common dynamics like unique biomarkers, unmet needs and priority approvals.

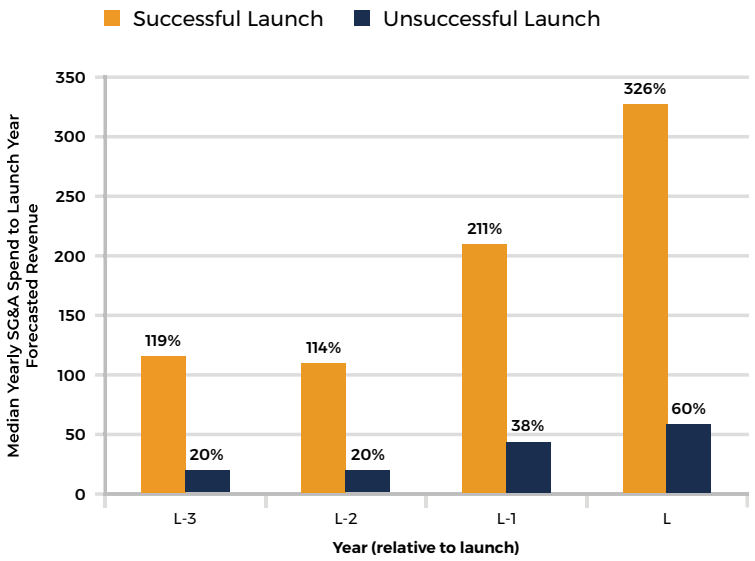
The changing reimbursement landscape has been a big driver of this trend with many payers automatically assigning new-to-market blocks at launch to manage access to costly new products. Those blocks typically extend six months, creating time for in-depth reviews by pharmacy and therapeutics (P&T) committees. Despite these relatively new levers of cost control, early education and conditioning remain critical. Even the newest drugs will be covered based on exceptions for medical need, and preparing a market takes place on a horizon of years, not months.

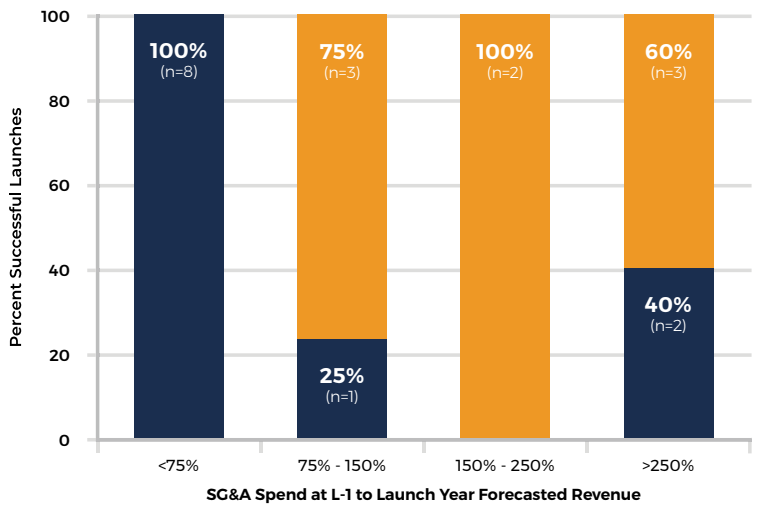
By pushing the investment later and later, companies are missing out on the value creation cascade that typically starts three years before launch and increases significantly one year out.

Syneos Health™ recently compared the investments of 19 biopharmaceutical companies that were launching their first products. It found that companies that spent a minimum of 75 percent of their launch-year-forecasted revenue during L-1 had higher rates of launch success. Even more importantly, not a single company that spent less than 75 percent of their launch year forecasted revenue in L-1 achieved a successful launch.

As a final analysis, we compared SG&A spend of companies that had a successful launch to those companies that did not. Specifically, the median SG&A spend of successful companies was ~120 percent of their launch-year-forecasted revenue in L-3 and L-2, ~210 percent in L-1 and ~330 percent in the launch year. In contrast, the median SG&A spend for unsuccessful companies was less than 40 percent of their launch year forecasted revenue in each of the years preceding launch and only 60 percent in the launch year.[32]







Launching Regionally

In 2019, the home office will start getting smaller.

Pharmaceutical innovators are increasingly looking at models that push decision-making and resourcing into regional authorities at a moment when their healthcare provider counterparts are doing the same.

The NHS is restructuring to give significantly more control to seven regional directors who will be responsible for the complex triple bottom line of quality, finance and operational performance. Japan is recalibrating its traditional national quantitative approach to care decisions with a new regional approach to qualitative health and quality-of-life targets. In the U.S., continued consolidation of both payers and providers has created significant disparity between regions in everything from metrics to access to approach to care.

So, how do pharmaceutical companies serve these increasingly distinct regional decision-makers? They create their own responsive and right-sized regional teams.

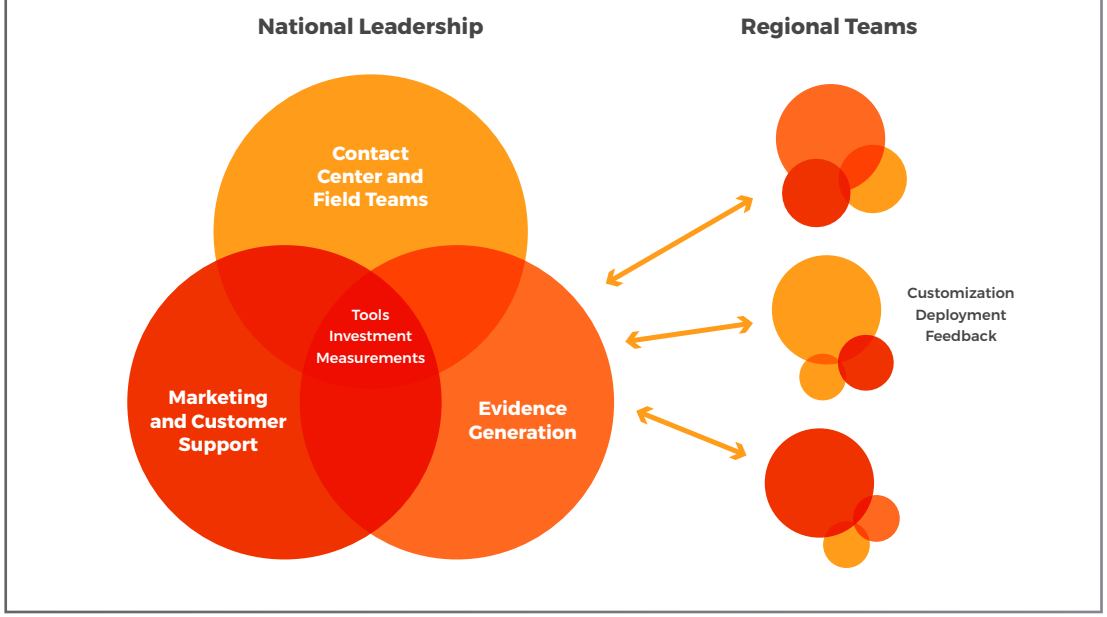
The first wave of change was giving regional sales mangers operational control of resources (not just sales accountability). In the next wave, marketing and evidence will go regional, and sales will take on an even more resource-flexible model.

Centralized global or national marketing experts will focus on building core tools, market sizing and comparative metrics. They'll leverage market simulation and testing to develop data-driven messaging and creative packages. The regional communications lead will be a channel marketing partner to the regional sales manager, able to quickly and effectively customize and deploy content that is most relevant to regional decision-makers.

Evidence will go more regional as well. 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.

Regional sales managers will move from making decisions on headcount to field force mix (e.g., reimbursement specialist, clinical educator, sales rep, etc.), contact center strategy and multichannel resources. Some of those contact centers will become hybrid regional hubs where teams make outbound calls/emails, host virtual-detail appointments and go into the field to solve problems at specific practices. Others will turn to local case managers who will be focused on navigating all regional and global resources across evidence, marketing and sales.

New Model Right Sizes Evidence and Support in Market



Speed to Uptake—or Exit

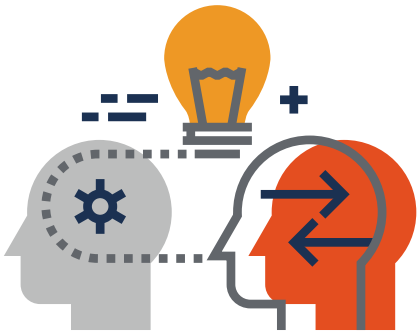
Launches were once planned around a promised hockey stick of growth that took a low curve up the market-entry blade until it hit an inflection point and quickly started a steep climb to the blockbuster finish.

Today, increased innovation, competition and payer control have changed the expectation for sales performance. In this new era, initial value has to be realized more quickly, and sustainability needs to be projectable over time. That's leading to new metrics that redefine performance.

For companies focused on a first or second commercial drug, those metrics also support an additional strategic component of launch: exit.

In 2019, every early innovator's launch plan needs to include strategies and associated accountabilities for proactive exit planning. Those exits can include true acquisition strategies as well as strategic outsourcing and partnerships.

Value: Uptake + Enthusiasm



Uptake:

Speed to significant physician trial

- Market readiness
- Segment awareness
- Relevance of evidence
- Initial trial against time horizon

Enthusiasm:

Durability of perceived impact and value

- Real-world delivery of value
- Percent use by median physician
- Influencer adoption
- Patient persistence beyond category standard

Future Ready

Questions and Discussion for Relearning Launch

Are we right-sizing risk vs. opportunity? Have we used data to simulate the market impact of different levels of education and spend?

Is the market appropriately prepared for our coming launch? Do doctors and payers understand the need, the science and the possibility for new interventions?

Are we appropriately supporting major regional decision-makers? Are our teams on the ground empowered to customize content, evidence and tools for them?

Have we revisited our launch metrics in this complex new landscape? What is our #1 lag metric for launch; what does success look like at a one- and two-year horizon?

SEARCH FOR THE RIGHT PATIENT

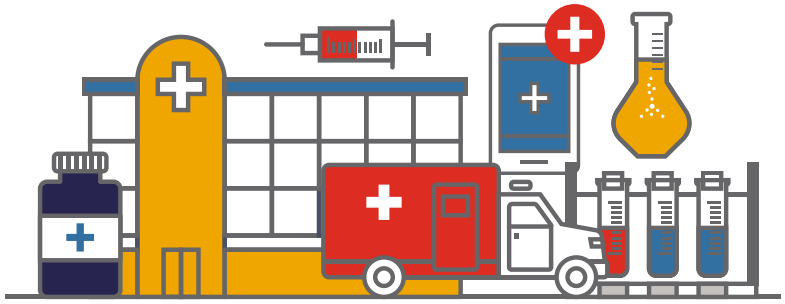
In 2019, data is taking on science. The most important insight won't be how a drug works, but who it works for. Systems, media and disruptors are getting much more sophisticated in how they find, engage and support those patients with the best choices and experience just for them.

Search For The Right Patient | Dynamics

The Personal Label

Today, drug, device and digital therapeutics makers don't want to try to own an entire category. Instead, they want 100% of the patients in a particular population.

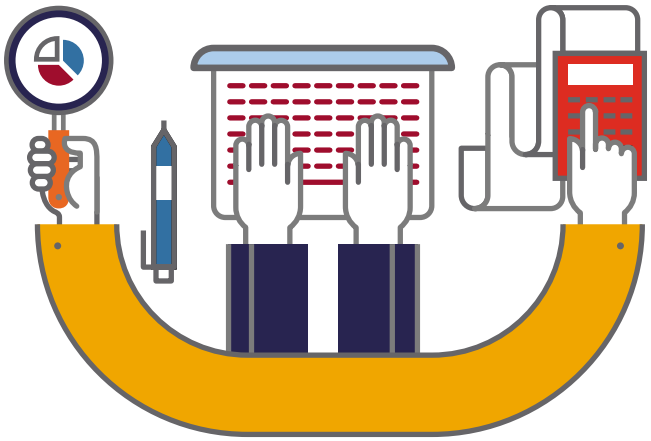
(READ MORE ON PAGE 32)



A Journey in Claim Codes

Healthcare leaders are building patient journey maps that offer unique, nuanced understanding of real-life experience via claim codes and search data.

(READ MORE ON PAGE 33)



New Seekers of Evidence

Headline-grabbing healthcare mergers don't just create new negotiation levers based on size and scale. They also give new parties a vested interest in understanding what works for their target populations.

(READ MORE ON PAGE 34)

New Levers of Local

The foundation of clinical recruitment in 2019 will be a digital ecosystem that delivers relevant content and support. Patients will find trials through hyper-local search and social media that recognize their interests and influencers.

(READ MORE ON PAGE 35)


SEARCH
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THE
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PATIENT

The Personal Label

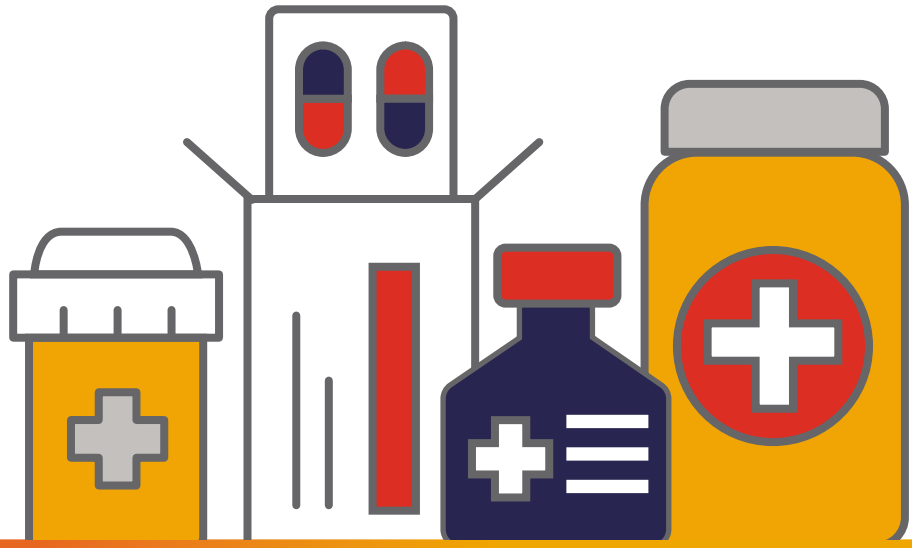
Label—and label extension—strategy is starting to shift from a broader and broader focus to a very specific one.

Pharmaceutical leaders and innovators are looking to identify indications for drugs that let them get treatment to the right patient, and only the right patient, in order to ultimately become the preferred approved treatment for that subsegment across a multipayer environment.

The new path to market share is hyper targeting, even with what would have once been mass-market drugs. Today, drug, device and digital therapeutics makers don't want to try to own an entire category—an impossible dream in any but the rarest of rare diseases. Instead, they want 100% of the patients in a particular population. Clinical and commercial teams are asking *Where can it make the most meaningful difference?* instead of *Where can this treatment make any kind of impact?*

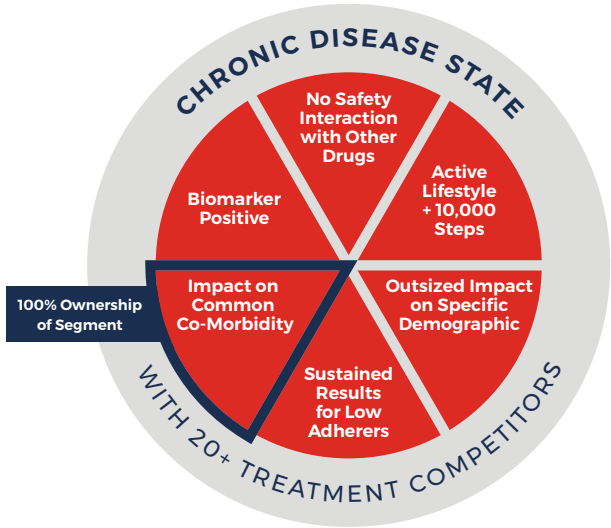
This shift is happening both because markets are getting more crowded and research methodologies are becoming more sophisticated. These more-personalized labels are enabled by testing against now well-known levers of scientific discovery, like biomarkers and co-morbidities, and increasingly against new ones, like behavior that can be tracked with diaries and wearables, and demographic subsegments.

Supporting and accelerating this shift is critical for companies because, in a future where rebates are increasingly constrained, market specificity will be the most critical lever of payer choice. The goal will be to be the one drug that is proven in a specific outcome for a specific population. The value is set on that unique—and niche—difference. In 2019, look for early leaders to sub-segment indications both by true differentiators and by investments in subset research that competitors just haven't analyzed yet.



From This is the Best Drug to This is the Best Drug for You

As categories become more crowded, innovators will increasingly look for advantages by understanding where their drugs have the most impact vs. trying to win on rebates and discounts. They'll stop fighting for a small piece of the big pie and start carving out high shares of very specific niches.



A Journey in Claim Codes

Rare answers—like those described on the last page and truly rare disease treatments—present an incredible challenge for innovators: How do you develop a drug for 5,000 people? How do you effectively test it, price it and find the patients who need it?

The fast lane to both patient identification and understanding in 2019 is data. Healthcare leaders are building patient journey maps that offer unique, nuanced understanding of real-life experience via claim codes and search data.

Clinical teams are able to use electronic healthcare data to pre-size potential clinical trial populations. They are increasingly leveraging de-identified, clinical and genomic data to estimate the number of patients that match specific criteria and see a comprehensive aggregated picture of the cohort. They can go further to identify sites that have eligible patients based on real data. All these lenses make it possible to more quickly find patient populations for even rare health challenges. They also help innovators determine early if there's a large enough patient population in a hypothetical cohort to support meaningful evidence.

In the commercial space, teams have a stronger understanding of what doctors are challenged with when it comes to rare diseases and target populations. Practices see those patients extremely infrequently and may not have an answer, treatment or even diagnosis ready at hand when they do. So, innovators are getting more proactive about supporting those healthcare professionals at right-now, relevant moments. They're offering physicians and networks electronic health record (EHR) algorithms and apps to uncover patients who could benefit from alternate treatments and using claims codes and search data to target field force resources when they're needed the most.

Disease Detectives Use Data to Find Patients in Need

Alnylam Pharmaceuticals works in ultra-rare diseases, like hereditary ATTR amyloidosis. Its marketing and sales operations teams work in part as disease detectives, using data to understand patient pathways. Its integrated customer-patient data-driven approach tracks 250 million patient lives' worth of claims data updated daily, plus lab results data that show which practices have tested for rare diseases. AI integrates that data to identify possible diagnoses or disease accelerations. That intelligence can direct field force and non-personal activity, as well as refine resourcing to ensure they're there when patients need them most.[5]

New Seekers of Evidence

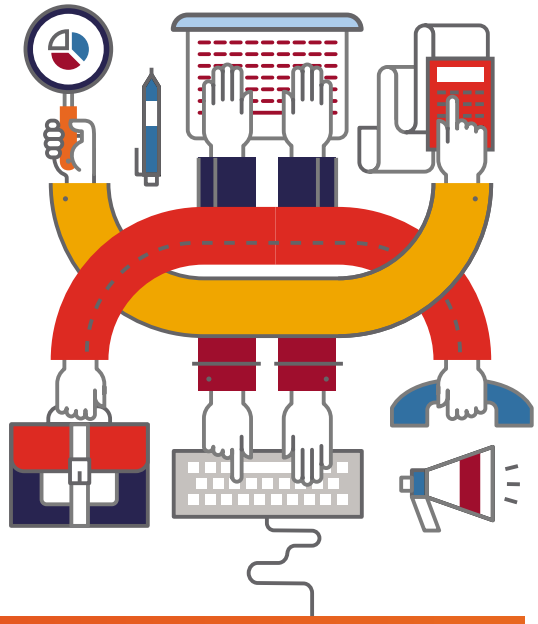
Mergers, acquisitions and partnerships continue to radically reshape the healthcare space.

From the headline-grabbing Amazon, Berkshire Hathaway and JPMorgan deal to Humana's acquisition of Kindred Healthcare to the Aetna-CVS integration, we're seeing healthcare players grow larger and deeper. This verticalization trend doesn't just create new negotiation levers based on size and scale; it also gives new parties a vested interest in understanding what works for their target populations to stabilize costs over time.

In 2019, look for these and other payer partners to both expect and invest in nimble, real-world research based on their unique member populations. Expect pragmatic trials, basket trials and competitive analysis to bring forward new decision-driving criteria.

For these organizations, the focus will turn from innovation to optimization, with a commitment to understanding what works, seeing where the gaps are and scaling that knowledge across networks.

In 2019, we expect to see companies like Humana and Kindred evolve their clinical research from broad questions about new tools into a more standardized sequence of multi-site evaluation of impact against their insured populations. Disrupters, like Amazon and CVS, are likely to go even further, leveraging their real-world data to consistently optimize their formulary, approved therapies list and education to preferred healthcare/ hospital partners. Their ultimate goal: Stabilize costs over time.



Tackling the Tapeworm

Berkshire Hathaway Chairman Warren Buffett famously called health costs a tapeworm afflicting the U.S. economy. Healthcare spending in the U.S. will be almost 20 percent of GDP by 2025.[2] The new vertical integrations we're seeing in 2018—with more expected by 2020—are set to challenge that with a critical combination.

Ecosystems + Business Models

Amazon, for example, is expert at that holy grail of healthcare management: changing human behavior. Integrating that knowledge with real-world behaviors and healthcare best practices stands to create a new powerful system of nudges that blend easily into people's lives and deliver meaningful population change.

The CVS-Aetna deal transforms data from customer tracking into a core business asset. They'll be able to combine large claims datasets with the ecosystem of retail pharmacy and even clinic care to deliver high-touch, data-driven interventions.

If Walmart follows suit with a rumored acquisition of Humana[13], they'll have a similar actionable system in place

New Levers of Local

Clinical trial recruitment is changing in critical ways. It's becoming more data-driven, more doctor-involved, more creative and more local.

For decades, outreach was broad and sterile, left to the fine print in newspapers and repeated radio ads and cordoning off potential patient populations to the people who could be reached there.

Today's recruitment campaigns put the potential patient types at the center. They pre-identify the sites they're most likely to be near, profile their current journey and experience, and find the media and messages that are most useful to them.

The core foundation of clinical recruitment in 2019 will be a digital ecosystem that delivers relevant content and support. Patients will find trials through hyper-local search and social media that recognize their interests and influencers. They'll learn more on websites that offer live connections to medical teams and links to trusted sites, like clinicaltrials.gov.

Patient influencers will become an increasingly important part of recruitment. In 2019, we expect that every major recruitment campaign will include research into the social influence in the category, and the places and communities where potential participants are already learning about and talking about treatment choices.

These approaches are a standard part of patient engagement by commercial teams. Bringing those best practices to clinical is helping medical experts stand on the building blocks of what organizations have learned about engaging patients instead of recreating them.

End-to-End Trial Engagement

Leading-edge clinical patient engagement teams are thinking beyond recruitment to support for the entire experience. They're creating clever ways to help patients overcome burden, manage their day-to-day lives and even get to the trial site.

For example, more than 100 healthcare organizations are currently working with Uber Health in beta and pilot programs.[19]

In 2018, Uber Health announced that it would partner with Bracket to bring the ride-sharing program to the clinical trial space. Bracket can give research participants the ability to request a ride through a patient engagement app. Sponsors can manage access and payments so that participants don't have upfront costs and rides can be limited just to the study location.

The programs relieve stress for both patients and site coordinators, who otherwise need to manage logistical challenges on a case-by-case basis.

Future Ready

Questions and Discussion for Search for the Right Patient

What segment could this drug serve 100 percent of? Have we considered all aspects of segmentation—from co-morbidities to demographics to behavior?

Are we maximizing site level and EHR data for clinical trial participant and patient identification? Can the data tell us more about the real patient journey?

Should we approach major healthcare systems with new research opportunities? Can they cut our existing data against their patient populations for new insight?

Is our clinical organization leveraging the best practices of patient engagement that have been created in the commercial space?

DEMAND FOR DECISION-DRIVING INSIGHTS

In 2019, pharmaceutical leaders are passionate about the opportunity to create change—and seeking the momentum to act on it. Look for new calls to more quickly create business cases, advance institutional data fluency and infuse behavioral science in everything we do.

Demand for Decision-Driving Insights | Dynamics

Evidence for Action

Life science is expecting partners to come forward with perspectives that include competitive context, impact modeling and executional details that drive decision-making.

(READ MORE ON PAGE 40)

Fluency in Data

In 2019, healthcare leaders will undertake organizational commitments to fundamentally understand how data can be used and when to use it.

(READ MORE ON PAGE 41)

Push for Understanding

Healthcare organizations are beginning to recognize that they can't just turn interest on and trust that it will stay on. The new job will be to constantly refill the bucket of motivation.

(READ MORE ON PAGE 42)

Fight for the M in CMO

The increased need for medical and managed markets strategy may change the face of commercial leadership in 2019.

(READ MORE ON PAGE 43)


DEMAND
FOR
DECISION-
DRIVING
INSIGHTS

Evidence for Action

Life science leaders are managing pressure on time and resources at a moment when the velocity of change and opportunity is faster than ever.

In their new world of work, they're entering new markets, engaging new customers and leveraging new technologies. Often, they're collaborating with junior team members who don't share their breadth of experience and expertise. They're fighting to work across silos to access the richness of the experience within the broader organization.

It's in that climate that they face their no. 1 charge in 2019: validate unfamiliar approaches and drive change.

And yet, as we enter the new year, too many healthcare leaders are struggling with gaining strategic traction. The possibilities for action and investment are great but the clarity around how to move forward is not. They don't have a mandate for specific actions and don't feel empowered to make critical strategic calls.

Increasingly, they're expecting partners to come forward with content that's designed to make a clear, actionable case to executive leaders. Those perspectives have to include the competitive context, impact modeling and executional details that drive decision-making.

Three Things Life Sciences Leaders will Expect from Commercial Partners in 2019:

Fast, deep perspectives
Answers to the most time-critical questions fueled by real-world insights and delivered in days or weeks

Fascinating insights
Deep, new understandings of a healthcare stakeholder or relationship that instantly align their organization

Proactive possibilities
Relevant, custom ideas routinely brought forward to deliver on company strategies in compelling new ways

Fluency in Data

A recent study[21] by Healthcare Executive Group (HCEG) found that the biggest challenge for healthcare leaders in 2018 is leveraging clinical and data analytics.

They cited the broad-reaching issues of wrangling large data sets, working across data silos and extracting data that's meaningful to different segments of customers.[42]

Most healthcare companies are deluged with similar research. That hasn't made finding new answers automatic or easy. In fact, as compelling as some data sets may be on their own, they don't easily come together to form a single view of a patient or marketplace.

Leaders are investing, but few have been able to align their teams around the most critical questions to answer or map internal and open data to each of those key challenges.

In 2019, we expect those same leaders to put a finer point on the challenge: To gain fluency at the organizational level, life science companies must make commitments to fundamentally understand how data can be used, and know how and when to use it.

Their ultimate goal: establishing a real-time window that uses data to show the next best action for every key stakeholder. For clinical teams, that might mean being able to tell a doctor how a particular patient is most likely to respond to the treatment or suggesting remaining questions to be answered within a trial design. For commercial teams, it could mean simple redirection for frontline teams, like answering, "How do I best communicate with this practice?" Or, "What message or solution will be most compelling based on their most recent actions?"

To improve fluency in 2019, we're seeing more small multidisciplinary teams come together to get hands-on with data possibilities and pilots. A typical program will include three aspects of experience and expertise.

1 **Inspiration**
Ignite desire for change by showing what's possible.

2 **Ideation**
Instill the sense of ownership through collaborative participation.

3 **Co-Creation**
Break down the silos by co-developing a model/pilot.

Why the Promise of Big Data Hasn't Delivered Yet

TechCrunch

"Big businesses have absorbed Google-style tech, but are only just beginning to adopt Google-style thinking alongside it."[6]

We're not moving fast enough to change.

Push for Understanding

In 2019, the expectation for a data-driven understanding of who, where and when to connect will remain strong. But the big driver of change will be *how*.

Look for a new focus on how behavioral science can unlock real change. Both clinical and commercial teams will invest in activating the ability to fuel motivation by understanding the psychological and social barriers that block behavior change. They'll amplify the strength of their communications strategies by embedding evidenced-based nudges and tactics designed to influence choices and behaviors.

Although the science of behavior isn't new, it's gained new attention in recent years as a way to help people act on the healthcare decisions they make for themselves and sustain the resilience to try and try again. In 2019, healthcare organizations will recognize that they can't just turn interest on and trust that it will stay on. The new job will be to constantly refill the bucket of motivation, creating the context and consistent support that will turn that interest into commitment, commitment into action and action into resilience.

Look for behavioral science to evolve and upgrade even small aspects of patient and physician engagement. Teams that understand motivational style will more effectively segment their contacts and make small changes in messaging to enhance motivation through simple behavior triggers.

Want to Learn a Little About Yourself?

There are two distinct styles with which people think about and approach their goals:

Achievers
are motivated by hopes, aspirations and the need to grow.

Defenders
are motivated by duties, obligations and the need to stay secure.

More than 25 years of research has shown us how to communicate to each motivational style. What's yours?

Fight for the M in CMO

Who should drive decision-making in the commercial space?

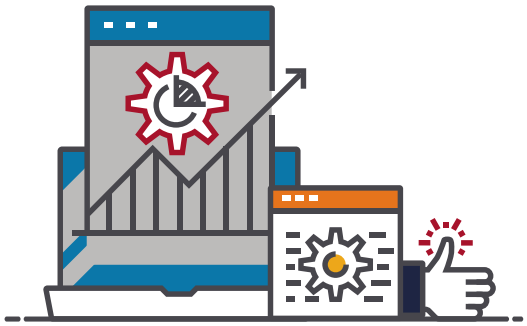
For decades, those leadership roles have sat largely with CMOs, chief marketing officers. But as industry decision-making moves from clinical differentiation to value differentiation, more life science innovators will question what the most relevant pedigree is.

Will that mean a fight for the M in CMO between managed marketing, medical and marketing leaders?

Given the rise in the profile of market access and the fact that reimbursement and economic barriers have become a critical aspect of development, managed markets experts are well positioned for new, higher-profile roles.

The impact of medical affairs is expanding as well. Those experts are engaging payers, practices, advocates and even patients—giving them potentially the most comprehensive view of the scientific and support needs of all stakeholders. Importantly, they're also the most direct bridge to clinical teams, fueling patient-centric information and evidence development.

Decision-Driving Data Mining at Celgene



Celgene is actively fueling a data-curious culture, able to make decisions in innovative new ways. The biotech firm built an organizational capability known as IKU (information, knowledge, utilization) to manage healthcare data as a core asset and harness its derived insights to drive decision-making across the entire organization.

The platform has two basic modules: Explorer, which scrapes and catalogs data across the organization, and Analyzer, which provides the tools to execute queries and research against that data set. The program breaks down the traditional silos that data would have been collected in and creates a bigger, cross-organizational picture of what's truly available—both directly within Celgene and via partnerships. And, it includes more than just data. Inside the system, users can also access best practices, business rules and existing computer code to advance projects more quickly and effectively.[36]

Future Ready

Questions and Discussion for Demand for Decision-Driving Insights

Where is our organization hampering clarity and agile decision-making? What kinds of evidence or articulation would help us move forward more quickly and effectively?

Are we leveraging data across our organization? Do all the roles that should act like confident data navigators feel like confident data navigators?

Have the principles of behavioral science been fully embedded in all of our clinical and commercial communications? Do we really know what motivates people?

Are all the M's—medical, managed markets, marketing equally heard in the strategic direction of our commercial organization?

REWIRED HCP

The profession of provider is radically changed as we enter 2019. Physicians find themselves working with less control, higher financial stakes and increasing mental health challenges, all in a climate with more information at their fingertips and less time than ever.

Rewired HCP | Dynamics

A Change in Control

Increasingly, treatment choices are moving from the exam room to the C- and D-suites. Here, executives are defining detailed formulary and algorithm of care expectations for huge swaths of employee physicians and their patients.

(READ MORE ON PAGE 48)

The Unhappy Profession

Today, two-thirds of U.S. 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.

(READ MORE ON PAGE 49)

A New Era of Evaluation

Changes introduced by the Centers for Medicare & Medicaid Services (CMS) have compelled some high-focus strategy shifts at many large providers, including increased system interoperability and reimagined use of physicians. Other CMS changes will promote value-based care.

(READ MORE ON PAGE 50)

The Attention Famine

There's a massive discrepancy between the amount of available content and the capacity we have to process it. For physicians, the challenge is even greater: the amount of clinical information is growing every year, multiplied by additional real-world data.

(READ MORE ON PAGE 51)


Rewired
HCP

A Change in Control

Physician authority and autonomy are declining.

Today, most physicians are employees rather than business owners. Cost pressures have made private practice less tenable financially, leading providers to join larger group practices, physician networks and hospitals in huge numbers.

As they move, so does their prescribing authority and overall autonomy. Increasingly, treatment choices are moving from the exam room to the C- and D-suites where executives are defining detailed formulary and algorithm of care expectations for huge swaths of employee physicians and their patients. Their overall goal: align physician behaviors to reduce medical variation, improve outcomes and satisfy various global payment reforms.

Many doctors, though, are still dealing with the professional whiplash of moving from an era of doctor as independent expert to doctor as carefully directed employee.

In the oncology space, the acquisitions and business challenges are continuing in huge numbers. A 2018 report[3] from the Community Oncology Alliance found that over the last decade, 1,653 community oncology clinics and/or practices have closed, been acquired by hospitals, undergone corporate mergers or reported that they are struggling financially.

In primary care, treatments are changing the role of physicians as much as administrative oversight. Primary care is being flooded by biologics that have new indications for chronic disease. These general physicians are dividing into two camps: those who become triage specialists and quickly direct potential biologics users to specialty partners and those who evolve their practices to become experts in the detailed patient identification and reimbursement advocacy work of biologic products.

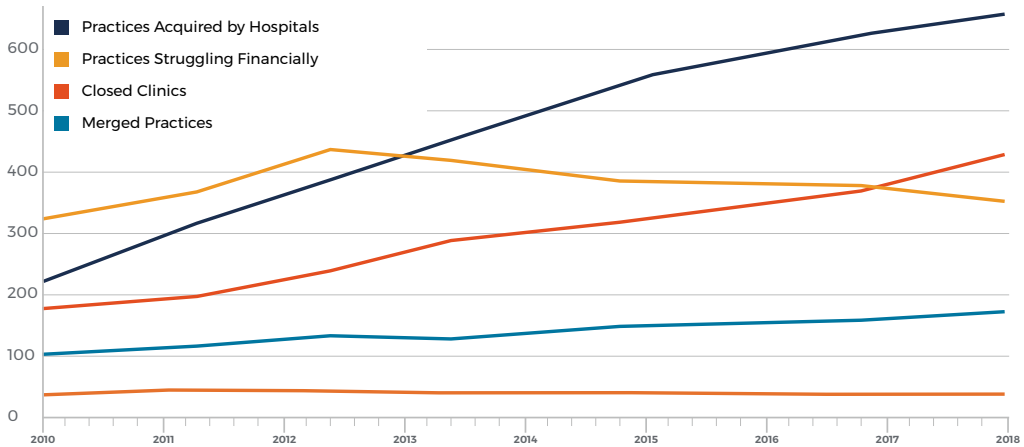
The Data on Decision-Support Deviations

A recent study[22,29] at Cedars-Sinai Medical Center divided 26,000 patients into two groups: those whose doctors followed clinical-decision support prompts in the EHR and those whose doctors did not. The results showed the dominance of population-wide data.

For patients whose doctors did not follow clinical-decision support prompts in the EHR:

- 29% complications
- 6.2% length of stay
- 14% hospital readmissions
- 7.2% costs

Growth in Acquisitions of Community Oncology Clinics Continues at a Steady Pace[7]



The Unhappy Profession

The mental health of healthcare providers is coming into sharp focus as we enter 2019.

Today, two-thirds of U.S. physicians report that they're burned out, depressed or both.[7] Physician suicide rates are double that of the general public.[18] Doctors say they're overwhelmed by the stress of the job, the constant influx of information and the endless administrative tasks. Add to that the inherent stress of a role that involves trying to save and extend lives and you can start to see the picture of a profession in crisis.

This job dissatisfaction doesn't hurt just professionals. Increasingly, it's impacting their patient relationships, as well. A recent Medscape study[20] found that a physician's level of happiness sets the tone for patient interactions. For example, of those cardiologists who expressed feelings of burnout and/or depression, here's how they said it impacts their patients:

Newly published findings indicate that burnout is also associated with an increased risk of patient safety incidents, poorer quality of care and reduced patient satisfaction.[37]

34% I am easily exasperated with patients

32% I am less engaged with patients

29% I am less friendly with patients

14% I express my frustration in front of patients

Survey of 15,000 Doctors: 42% burned out; 15% depressed[7]

Highest Rates of Physician Burnout by Specialty:

- **48%** Critical care, Neurology
- **47%** Family medicine
- **46%** Obstetrics and gynecology, Internal medicine
- **45%** Emergency medicine

Lowest Rates of Physician Burnout by Specialty:

- **34%** Orthopedics
- **33%** Ophthalmology
- **32%** Dermatology, Pathology
- **23%** Plastic surgery

2x

- **The risk of portraying low professionalism** → Leads to poorer quality of care
- **The odds of involvement in patient safety incidents** → Symptoms of depression and emotional distress increase by another 2x
- **Increase in low patient-reported satisfaction** → Even higher (4.5x) for HCPs that exhibit traits of "depersonalization"

A New Era of Evaluation

The Centers for Medicare & Medicaid Services (CMS) in the U.S. are continuing to quickly rewire how hospitals and sites of care are reimbursed.

These changes are set to significantly alter what metrics these providers are focused on and how they'll measure both care and partnership.

Since its start in 2015, the Medicare Access and CHIP Reauthorization Act, or MACRA, has been a silent revolution in payment reform. The potential impact on hospitals could be reimbursement cuts as high as $250 billion by 2030.

Preparing for and evolving to MACRA has become a high-focus strategy at many large providers. Its top goals: reorienting how they use physicians and physician extenders, interoperability of data and systems, reducing costs and improving population health management.

Meanwhile, the Centers for Medicare and Medicaid Services Innovation Center (CMMI) is continuing its five-year test of innovative payment strategies that promote high-quality and high-value cancer care. The program started in 2016 and initial findings are expected to be reported in 2019.

Eventually, these shifts are expected to have a significant impact on promotion. Those interactions will evolve to more frequently engage value-based decision makers with new population-specific metrics and stronger pushes for additional rebates.

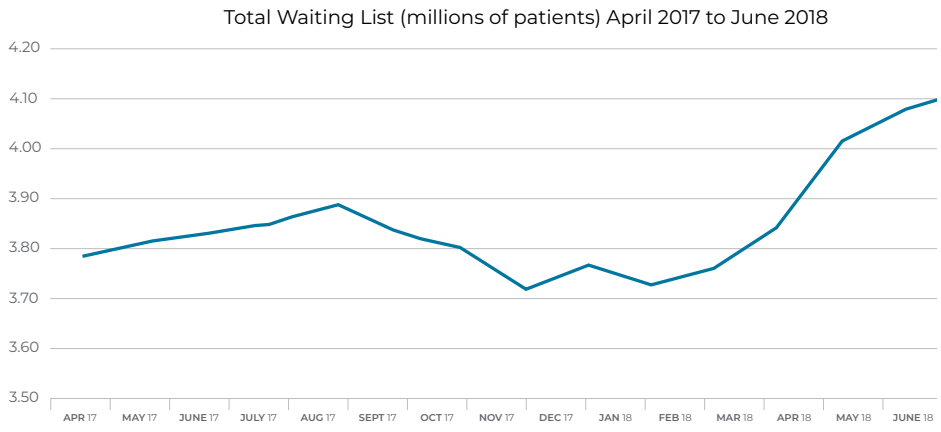
In addition to sharing the U.S. focus on cost containment, the UK is also looking at speed. The NHS recently created an urgent plan to send more patients to private providers for routine procedures to meet its service target of treating 92% of patients who need elective care within 18 weeks.[25]

Today, more than 4.11 million people are waiting for care and there are increasing concerns the NHS Trusts are not prepared for the additional pressure of the winter months.[24]

MACRA's Proposed 2019 Quality Payment Program Year Three Rule is Focused On Three Significant Changes:

1. Increasing the percent of the Merit-based Incentive Payment System (MIPS) score that is based on cost performance
2. Requiring providers to bring electronic healthcare record systems up to 2015 Edition Certified Electronic Health Record Technology (CEHRT) standards
3. Opening reimbursement eligibility to additional providers, including physical therapists, occupational therapists, clinical social workers, and clinical psychologists

The Number of Patients Waiting for Care in the UK Has Increased Sharply[25]



The Attention Famine

Our culture promotes a permanent state of multitasking.

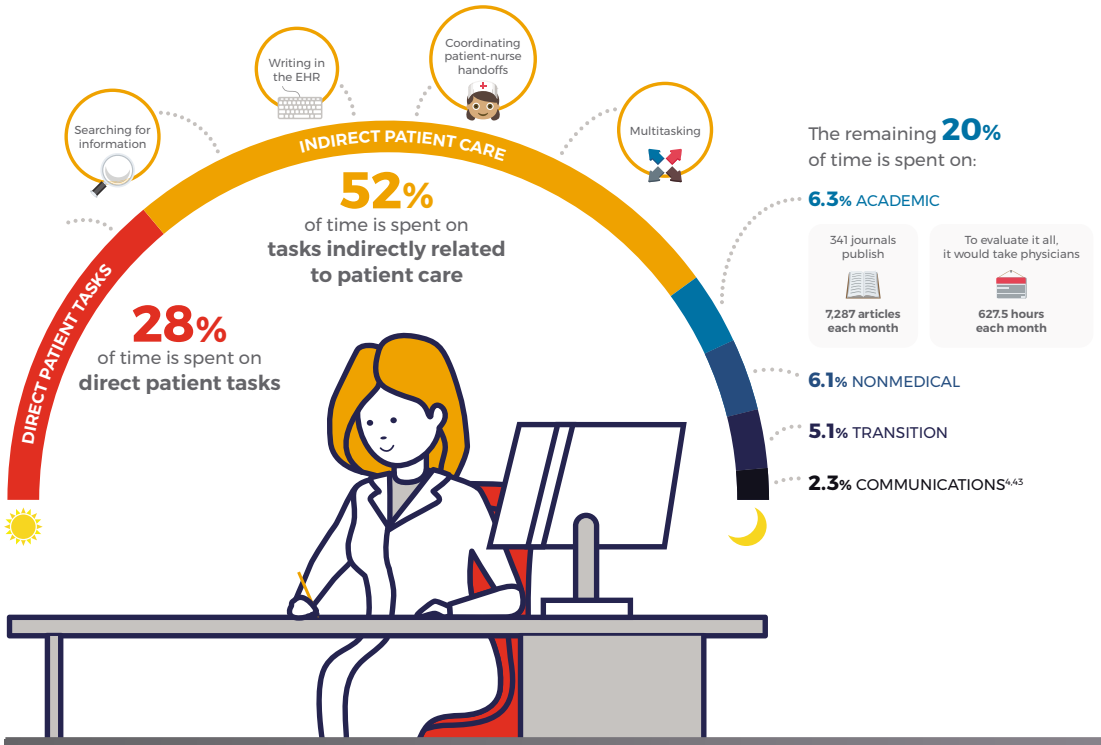
We have access to hundreds of TV channels, thousands of pieces of content on streaming sites and the 300 hours of new video uploaded to YouTube every minute. We see about one million marketing messages each year, and spend, on average, 13 hours on email and 14 hours on social media each week.

We cannot pay attention to everything. Recent research notes that our brains receive about 11 million bits of data per second, yet we're only able to process 50 bits per second.

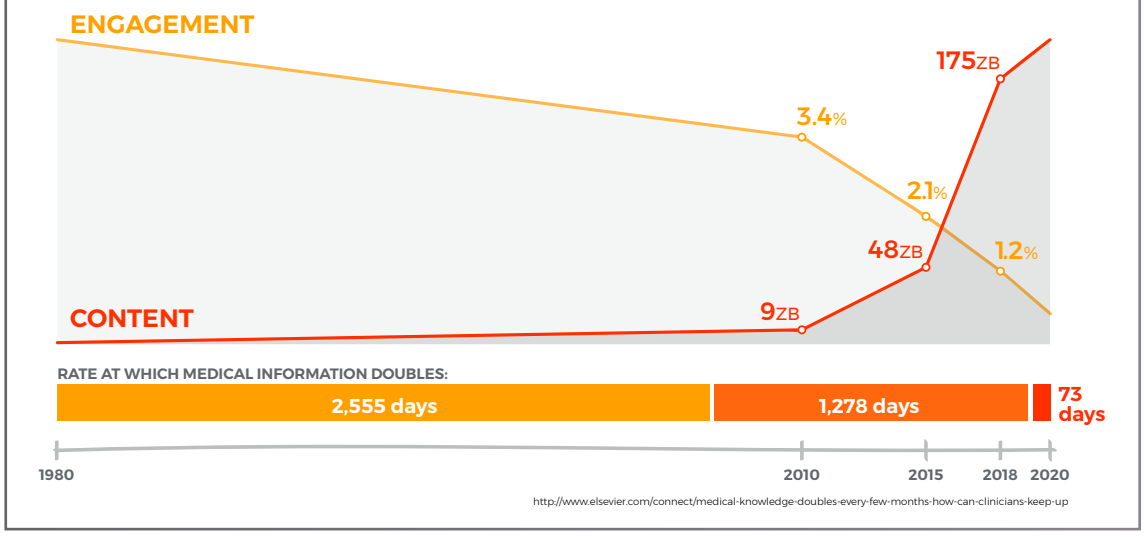
There's a massive discrepancy between the amount of available (and growing) content and the amount of capacity we have to process it.

For physicians, the challenge is even greater. The amount of clinical information is growing every year—multiplied by additional real-world data and evidence. The channels and sources in which it can connect with peers continues to expand. The expectations for documentation, cross-checking and logging are higher than ever.

Only 53 percent of doctors think that the increase in medical information makes them a better doctor. A recent Harvard Business Review article[11] explained it best: "Imagine an oncologist with more than a decade of practice experience is evaluating a lung cancer patient today. During her training years ago, there would have been a handful of therapy options to consider. Today, there are dozens of additional options, in addition to hundreds of open clinical trials, each representing a potentially more effective treatment for the patient. Not only does she have to know about these new drugs and the active clinical trials, she also should be up-to-date on all of the published articles in this area so she can understand the science behind each therapy option in order to make the best decisions for her patient."



Regardless of Attention Span, as the Volume of Content Increases, Our Consumption of it Can't Keep Pace[14]



Future Ready

Questions and Discussion for Rewired HCP

What can we do to help physicians evaluate and act on population health advice?

Are there ways we can make glut of scientific information easier to access and digest?

Are our messages and support mechanisms lined up with the metrics and measures our physician and health system partners are accountable for?

Can we re-inspire physicians with some of the reasons they selected this profession?

RELIEVING BURDEN

The weight of the work is piling up on our most critical stakeholders. In 2019, old and new players are stepping in with new strategies and services that reduce friction, complexity and inconvenience across the clinical and commercial landscape.

Relieving Burden | Dynamics

Year of the Problem Solver

To best serve practices in this resource-starved, formulary-first era, field teams are spending less time selling a product and more time on patient and practice support.

(READ MORE ON PAGE 56)

A Shift to Motivated Patients

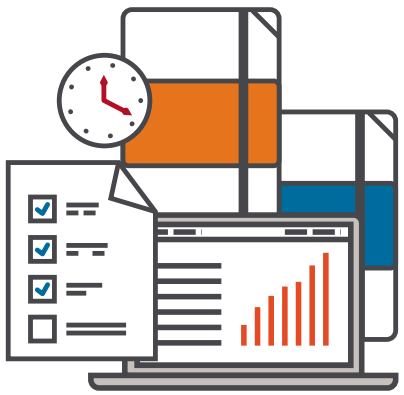
Healthcare innovators are empowering practices with both practical support, like reimbursement training, and one-on-one education. Patients accustomed to drive-by interactions with time-starved providers can now engage deeply with medical experts.

(READ MORE ON PAGE 57)

Becoming Sponsor of Choice

Trial sponsors are now vying to be the clinical partner that brings the kind of experience and feedback loop that sites value the most.

(READ MORE ON PAGE 58)



Streamlining the Process

More and more clinical teams will rely on eClinical mobile systems—which support both research operations and participant engagement—to reduce burden on patients, sites and clinical associates alike.

(READ MORE ON PAGE 59)


RELIEVING
BURDEN
BILL
BILL
BILL

Year of the Problem Solver

The environment our field teams are working in is very different than it has been in the past.

All-time low

- Access
- Physician choice
- Reimbursement

All-time high

- Complexity
- System hurdles
- Patient expectations

To best serve practices in this resource-starved, formulary-first era, field teams are making an important shift: from selling an asset to educating on a process. They're still talking about clinical differentiation, but much more of their in-person time is spent on patient and practice support.

Field teams and practices alike are dealing with two sides of the access challenge: coverage and complicated systems. Both of those have a significant impact on how prepared the office is for pull-through. Today's integrated field team is built to both deliver foundational education that reduces the complexity and on-demand service to combat inevitable friction.

Key experts—including field reimbursement specialists—have long-form meetings with office staff and clinicians to ensure that practices understand how to identify the right-fit patient and advocate for that through system and payer review processes.

Then, a contact center hub ensures that offices have one-call/one-text access to either immediate answers or a connection with a relevant medical, reimbursement, education or rep resource.

For personalized medicines, the infrastructure is growing even more complex and concierge-oriented. Personalized medications need personalized logistics that can include everything from shipping pick-up/drop-off to on-site patient education to how-to expert medical education.

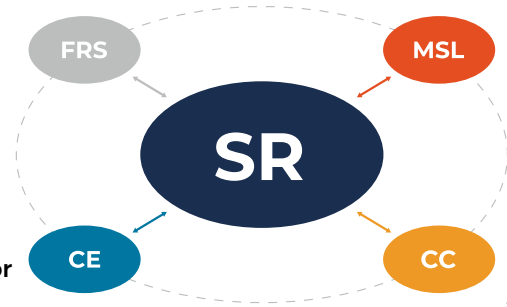
Today's Field Teams are Focused on Service that Delivers Right Now and Ongoing Office Support

Field Reimbursement Specialist

The navigator

MSL

The real-world science educator



Clinical Educator

The clinical "how to" for office and patient

Contact Center

The triage point for critical operational challenge

Sales Rep

The service connector

A Shift to Motivated Patients

The challenge in chronic disease was once: *How do I get my least motivated patient to start treatment?*

Today, physicians are facing a new question: *How do I get my most motivated patients on the right treatment?*

The possibilities of care are greater than they've ever been before. Doctors are navigating healthcare system barriers (like quantity capping and step edits), a surge of new clinical trials and pipeline opportunities, and entirely new choices in care—from digital therapeutics to chronic disease cures.

Highly motivated patients are also highly educated, bringing more ideas and options to every conversation. They want to know: Why can't we just do the best thing?

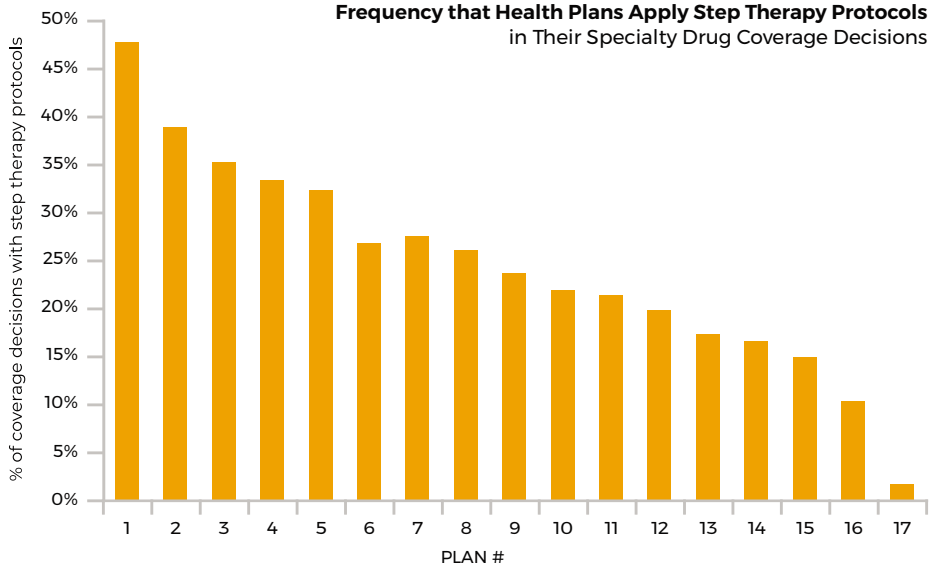
Healthcare innovators are empowering practices with both practical support and patient support. Those one-on-one conversations let patients accustomed to drive-by interactions with time-starved providers engage deeply with medical experts. For clinical research, those experts are clinical trial educators (CTEs). They go into the field to work with primary investigators on patient identification and support, and can also directly educate patients on the clinical trial. In the commercial space, clinical educators offer detailed training and support primarily for people managing chronic disease, and make physicians aware of available technology to enhance their ability to track patients' adherence.

Practices Navigate Inconsistent Step Edits in the U.S.

The Centers for Medicare and Medicaid Services recently authorized Medicare Advantage Plans to use step therapy protocols for Part B drugs. The policy launches in January 2019 and is intended to give Medicare Advantage Plans more leverage when negotiating with product manufacturers. This move is the latest in an increasingly complex landscape of step-edit design that encourages physicians to prescribe a less expensive therapy first and see if the patient does well—or fails—on it before moving to another treatment.

The journal Health Affairs recently reviewed publicly available coverage decisions issued by 17 of the 20 largest commercial health plans. They found that one in four coverage decisions included a step therapy protocol (1,208 of 4,809 decisions). But there was a huge variation—from 2 percent to 49 percent—across the included plans.[10]

Frequency that Health Plans Apply Step Therapy Protocols
in Their Specialty Drug Coverage Decisions



Becoming Sponsor of Choice

The landscape of clinical research has never been more crowded.

In this era, full of innovation and competition for scarce investigator resources, pharmaceutical leaders and innovators are finding that the first-choice group of investigators won't always be available. They're creating new strategies to both earn loyalty and build a growing bench of potential sites.

The new promise: be the sponsor of choice, the clinical partner that brings the kind of experience and feedback loop that sites value the most. For investigator teams, that means seamless onboarding, and for potential and committed patients, that means differentiated experiences, including everything from personal health dashboards to video learning to digital self-tracking.

The most critical part of site-centric planning is burden. Clinical teams are increasingly adopting three best practices as a more standard part of alleviating burden through trial design:

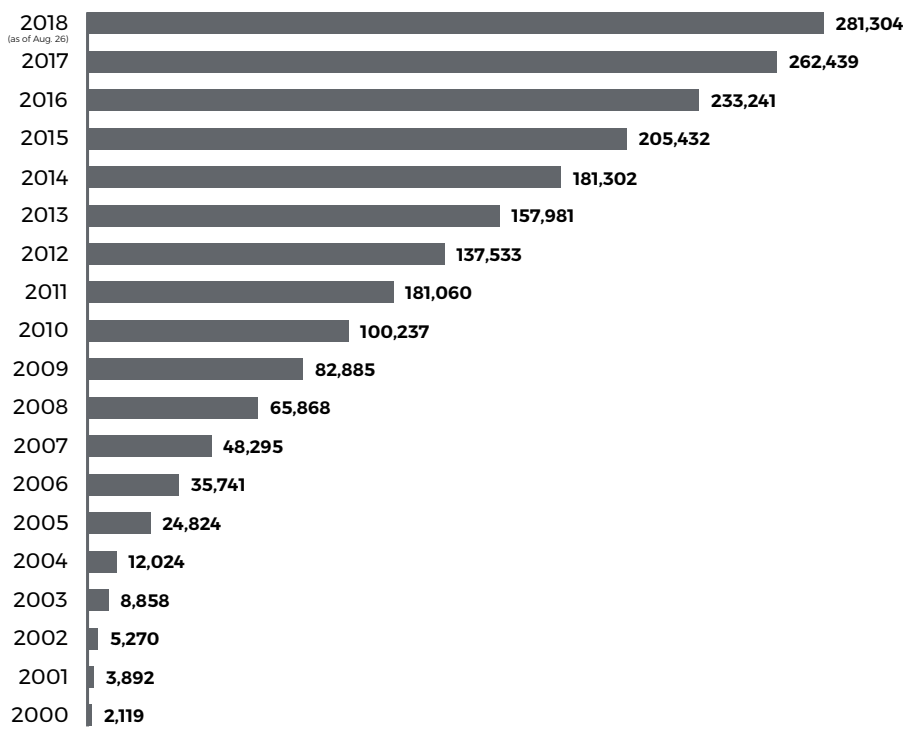
1 | **Collaborative design:** Co-developing protocols with advocates, sites and patients

2 | **Protocol feedback:** Leveraging new research techniques to calculate, weigh and score burden for every trial, and recalibrating to remove steps that would create too much of a negative burden load

3 | **Reducing disruption:** Creating innovative services that ease challenges that interrupt patients' lives, like transportation, time and logistics

Number of Registered Clinical Trials Continues to Grow Year Over Year

Total number of registered clinical studies worldwide since 2000[23]



Streamlining the Process

A recent report[31] found that, in the last decade, clinical trial complexity increased by nearly 86 percent: more paperwork, more documents, more expenses, more time.

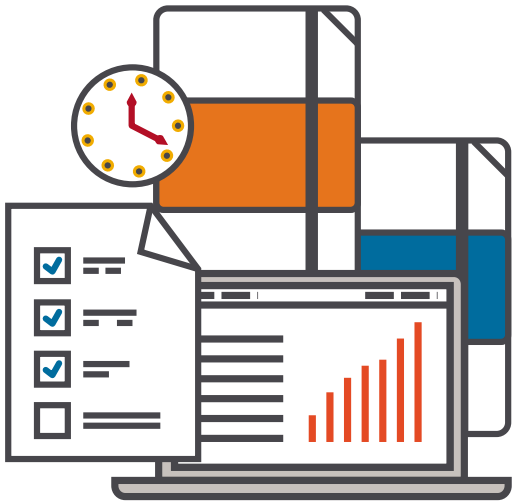
For many clinical teams, the tools they have had in place aren't nearly enough to keep up. Today, the average clinical trial relies on 25–30 different types of workflow solutions, and 72 percent of sites are using spreadsheets to track startup.[31]

In 2019, we'll see more teams expect e-clinical systems to reduce burden on patients, sites and clinical associates alike. The platforms present a complete digital workflow that can support both research operations and patient engagement.

In the short term, the biggest impact is the potential to eliminate source data verification (SDV) and simplify the documentation process at investigative sites. E-clinical suites are also fueling differentiated patient experiences, like the ability to accept electronic signatures/ e-consent and request virtual and video visits.

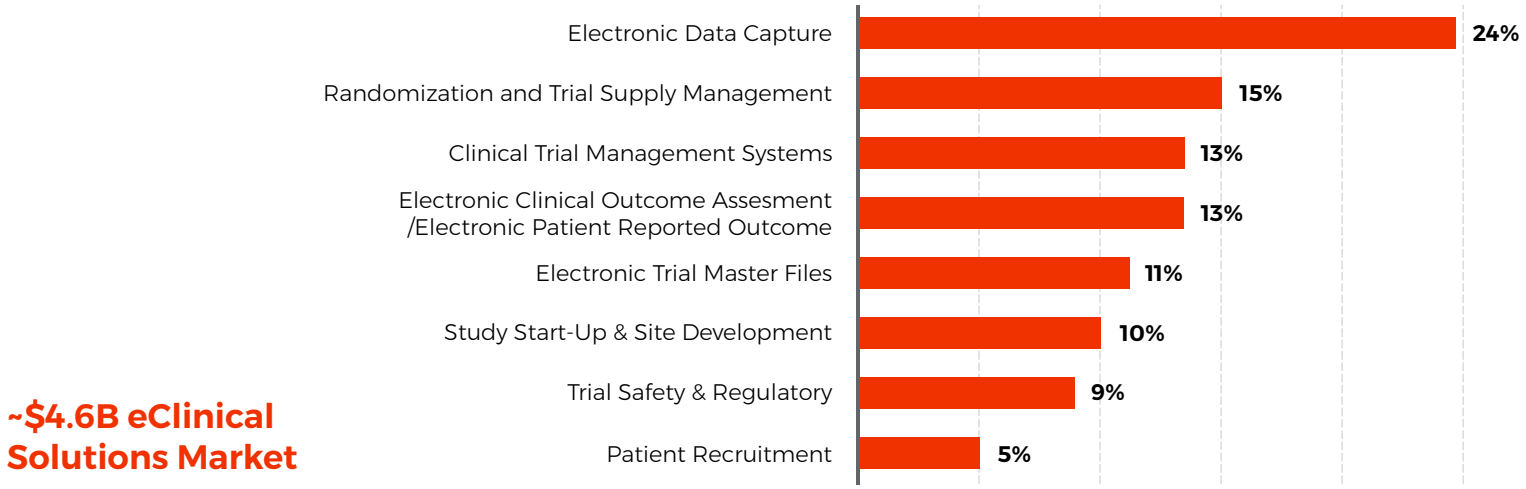
In the U.S., the e-suite systems are largely good news, allowing them to reduce paper recordkeeping and duplication. But the experience isn't all good for investigators. Large sites everywhere may have a daunting list of sponsor-specific logins and interfaces to track. Outside of the U.S., the suites largely interrupt a longstanding approach of simply entering clinical data into medical notes. Now, sites will need to do double entry of each data point.

The overall trajectory of the industry is toward integrating clinical trial data into electronic health records. That remains difficult because



of the fragmentation in that marketplace. Countries like the UK, Taiwan, Korea and Japan have been able to move faster with EHR-connected pilots because they share a more common national technology infrastructure.

Clinical Trial Management Systems (CTMS) and Electronic Data Capture (EDC) are the Most Prominent Early eClinical Solutions[31]



~$4.6B eClinical Solutions Market

Future Ready

Questions and Discussion for Relieving Burden

Have we fully integrated the newest experts—like field reimbursement specialists—into the commercial team? Are we getting feedback from practices on how well they're being supported in this new environment?

Which practices are most effective at writing prior authorizations? What can we learn about how they were prepared? How can we extend their influence?

Have we recalibrated our clinical trial experience from the site's perspective? What could we make easier, more white glove, or more informative?

Where can we use digital tools to make it easier for patients and sites to work with us? Have we audited and evaluated our clinical trial process against the latest digital tools?

VALUE PUZZLE

Debates about value may be old, but innovation, politics and data have re-energized it for 2019. People, payers and advocates want to know: Is it worth it? And who should pay?

Value Puzzle | Dynamics

Managing the Unmanaged

Some new treatments are converting once-terminal diagnoses into chronic conditions. These breakthrough drugs are creating a new category of aging patients, who are facing multiple health challenges and balancing active combination therapies and ongoing maintenance.

(READ MORE ON PAGE 64)

Price Populism

The Trump administration is focusing on reducing drug costs in two different ways: direct and global negotiation. The former seeks to reduce the size of the pie—the total cost—and the latter seeks to even the size of the pieces.

(READ MORE ON PAGE 65)

The Drive Toward True Price

We'll soon see more frank discussions on price 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.

(READ MORE ON PAGE 67)

Success Scenarios

Pharmaceutical innovators will actively advocate for value-based contracts, leveraging three strategic elements in particular: well-defined end points, short-term impact and collaborative data mining that creates a single-minded value impact for payer and manufacturer.

(READ MORE ON PAGE 69)


IN WHOM
VALUE
PUZZLE
SHOULD WE TRUST?

Managing the Unmanaged

In 2017, we saw a 21-year high in the approval of novel new medications.

Almost 60 percent of those were for oncology, including treatments that activate the immune system, replace genes or cells, and address the unmet needs of tiny, targeted populations. In the pipeline, there are 7,000 more new medicines, 74 percent of which are set to be first-in-class treatments.[26]

Some of these treatments are changing the very nature of disease, converting once-terminal diagnoses into chronic conditions. These breakthrough drugs are driving survivorship, and with it, creating a new category of aging patients who are facing multiple health challenges and balancing both active combination therapies and ongoing maintenance.

That innovation is both extending lives and stretching resources. The resulting financial burdens are fueling new questions:

- **For the innovator company:** how to effectively recover costs on the development of a novel drug for a small population?
- **For public healthcare systems and private payers:** how to manage costs to best support a diverse population of members or citizens?
- **For people and families:** how to pay for uncovered costs, ranging from treatments to transportation to home care?

For public healthcare systems and private payers, the answer in 2019 is active management of medical choices in all categories, even ones that were previously considered untouchable, like HIV and oncology.

That transition follows a typical pattern:

Unmanaged
↓
Formulary Review
↓
Prior Authorizations
↓
Preferred Products and Pathways
↓
Value

In oncology, we're seeing more payers engage physicians in understanding and acting on those value equations with capitated and risk-sharing models, as well as significant reliance on value frameworks, like ASCO, NCCN, MSKCC, ICER or ESMO.

In HIV, the partnership is increasingly patient and payer. Programs, like CVS Specialty HIV Care Management, are actively managing the entire lifetime of disease with engagement plans designed to close gaps in care and reduce overall healthcare costs. The CVS model specifically reports up to 13 times greater engagement from members, including following prescribed steps to improve lifestyle or effectively address health issues.[15]

Pharmaceutical innovators are supporting these shifts through the rapid growth of health economics research outcomes studies that include patient-reported outcomes data and perspective on QALYs (quality-adjusted life years). They're also spinning up new, powerful patient support programs that both help achieve outcomes and demonstrate new methods of intervention and engagement.

CDC's List of Chronic Diseases

One in two adults in the U.S. has a chronic disease and **one in four adults** has two or more.[33]

- Alzheimer's Disease
- Arthritis
- Breast Cancer
- Cervical Cancer
- Colorectal (Colon) Cancer
- Diabetes
- Epilepsy
- Gynecologic Cancer
- Heart Disease
- High Blood Pressure
- Lupus
- Obesity
- Prediabetes
- Skin Cancer
- Stroke
- Type 2 Diabetes

Price Populism

The Trump administration in the U.S. may make the future of pharmaceutical commercialization look very different in every country.

The administration is focusing on reducing costs two different ways: direct and global negotiation. In short, the former seeks to reduce the size of the pie (the total cost) and the latter seeks to even the size of the pieces.

Direct negotiation has a wide range of possibilities. To name a few:

- Removal of the noninterference clause in Medicare Part D, which would allow the Secretary of Health and Human Services (HHS) to intervene in the negotiations between Part D plans and drug manufacturers.
- Repeal of the Medicare Anti-Kickback Safe Harbor Statute, which would potentially reduce administrative fees by removing middle men from complex contracting.
- Extending co-pay programs to Medicare Part D, which would change the negotiating criteria for Part D to allow more pharmaceutical discounts to be transparent to enrollees and ultimately reduce out-of-pocket costs.

The global negotiation landscape is more complex. The U.S. is already making clear connections between trade and pharmaceutical pricing, for example, asking for the removal of restrictions on direct-to-consumer advertising of medicines in trade agreements with Australia and South Korea.

In future-facing statements, the administration has gone even further, saying "as we demand fairness for American patients at home, we will also demand fairness overseas. When foreign governments extort unreasonably low prices from U.S. pharmaceutical companies, Americans have to pay more to subsidize the enormous cost of research and development."

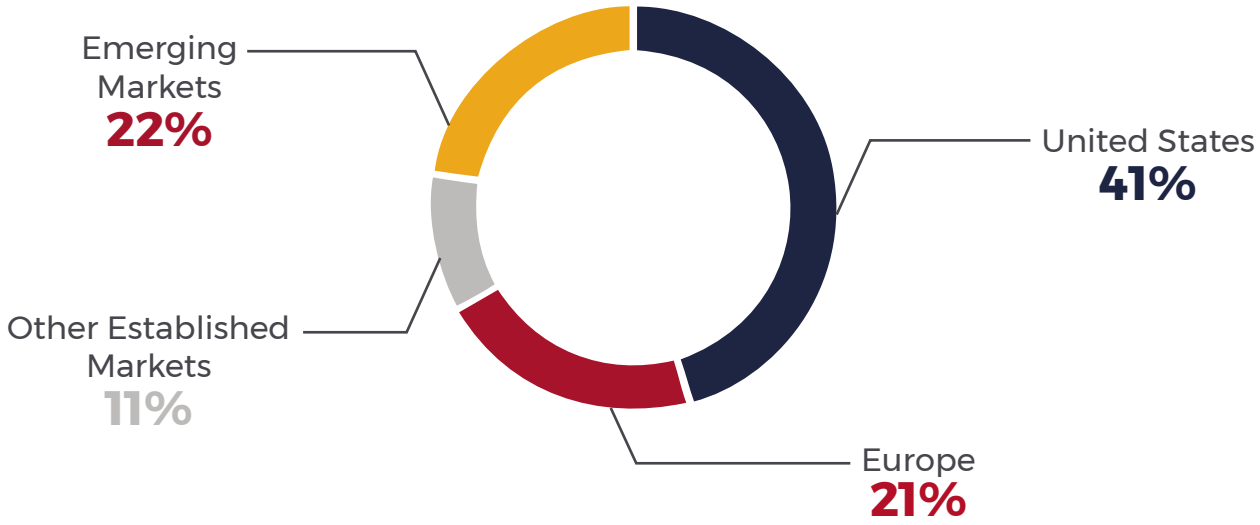
If these trend lines continue, two to three years from now, a U.S. launch is going to look much more like a European one. In the short term, the industry will push investment toward health economics and outcomes research (HEOR) as part of an integrated real-world evidence package for both payers and regulators.

We also expect to see new debates and fault lines around who should get what coverage. Those disputes could be geographic: *Why is a citizen of one country covered and a citizen of another is left behind*? They could also be by health challenge: *Why is treatment for a drug addiction free to a family, but treatment for cancer will bankrupt them*?

In 2019, cost will be more high-stakes, more emotional and more complex than ever before. Look for new conversations, new advocates and new algorithms that all try to point to the right next way.

The Current Shape of the Pie

Percent of global pharma market shares by region[41]:

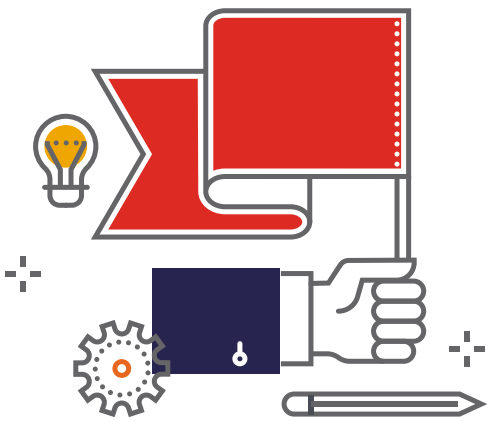


How Industry Leaders are Responding

Pharma is freezing prices
Pfizer went first. After a tweet from the president and a follow-on live conversation, Pfizer agreed to return drug prices to their pre-July 1 level and not increase prices before the end of the year or until President Trump's broader drug-pricing blueprint goes into effect. Novartis, Roche and Bayer followed suit. Merck announced it would drop prices on several drugs by 10 percent or more. To date, a total of 15 manufacturers have either lowered prices proactively or frozen increases.

Pharmacy is introducing new restrictions
Express Scripts added 48 new exclusions to its national preferred formulary to take effect beginning January 1, 2019. The excluded drugs include 22 therapies that have low-cost generic or biosimilar alternatives, and 12 instances of brand-to-brand competition where the drugs have the same active ingredient, but the excluded drug carries a higher net price. These exclusions include Gilead Sciences' triple-combination HIV therapy, Atripla, AbbVie's hepatitis C drug, Mavyret, and Sanofi's hemophilia treatment, Eloctate.

CVS announced in a recent white paper that it will use the value-based pricing system of the Institute for Clinical and Economic Review (ICER) to exclude some high-cost drugs from plans. It is initiating a program that will allow exclusion of any drug launched at a price greater than $100,000 per quality-adjusted life year (QALY). This approach will only apply to non-breakthrough designated drugs that have ICER-generated QALYs, which means it is likely a limited number of drug categories will be impacted (e.g., RA, PsO and MS).



(Note: The implementation of this program has been delayed to 2019 based on advocate and patient feedback.)

The Drive Toward True Price

How much does Drug X cost? That can be an incredibly difficult question to answer because the price varies by geography, coverage, hospital systems and specialty.

Nowhere is that price less clear than in the United States, where the complex system often involves five companies from drug development to placement in a specific patient's medicine cabinet. At each step, the number of actual companies branches out, each unique path governed by distinct contracts, discounts and access.

In 2019, one step may be collapsing—or changing significantly: pharmacy benefit managers (PBMs). The PBMs are a strategic pivot point in pharmaceutical pricing. They let large purchasers of drugs pool their demand to negotiate everything from costs to rebates to dispensing fees. But, they're also considered costly middle men.

The overall focus on reducing costs has made PBMs a consistent target of healthcare leaders and policymakers. Meanwhile, the data about who is using which treatment how often has driven significant M&A activity that may be changing—rather than eliminating—PBMs.

The biggest PBM headline of 2018 was the Cigna-Express Scripts (ESI) deal that signaled, if approved, the end of the last truly independent, large pharmacy benefit manager. Leaders of the two companies pointed to significant opportunities to align behavioral, medical and pharmaceutical benefit management through one advanced analytics lens aimed at better supporting individual members and better defining value based on real-world impact.

The deal is just one example of an industry in transition. The leading PBMs have all merged with managed care (OptumRx PBM is a unit of insurer and healthcare provider UnitedHealth; Caremark has been part of CVS Health since 2007 and CVS Health is currently completing the acquisition of insurer Aetna). That gives them a new platform to show relevance and value, but it is also set to burst the bubble between net and gross pricing, creating more transparency to both what drugs cost and who receives that revenue.

These big system-level deals aren't the only examples of increasing price transparency. In 2019, we'll see more frank discussions on price coming to the point of care. EHRs can show doctors the anticipated out-of-pocket and system costs of drugs. In the U.S., more people are joining health savings account-style health plans that expose them to the real cost of medications and procedures. In October, President Trump signed into law the Know the Lowest Price Act and the Patient Right to Know Drug Prices Act. Both aim to end the drug industry's "gag rule" of pharmacists, which prevented them from discussing cheaper price options—like whether a medication may be less expensive if using insurance or paying out-of-pocket—with consumers.

American Voters Weigh in on Price

A Fall 2018[35] poll found that many Americans believe drug prices are too high. They actively support more choices and more transparency:

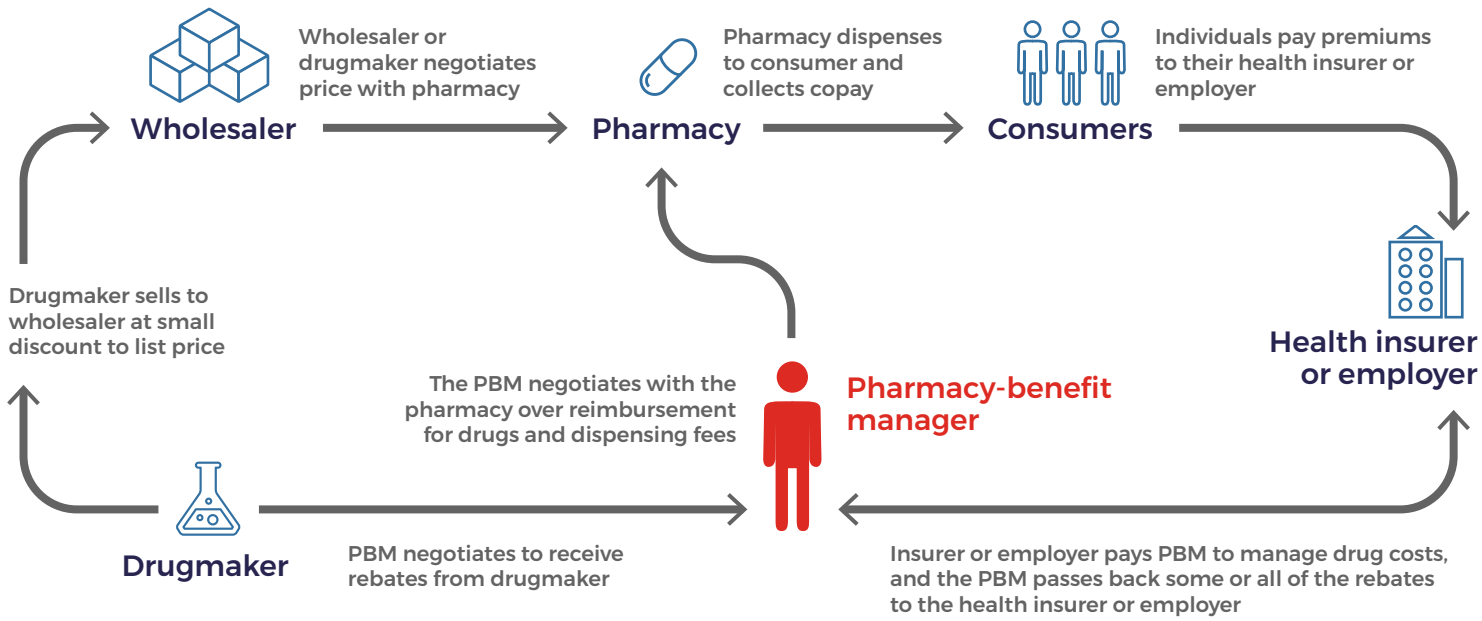
2 out of 3
Americans support increasing generic and biosimilar competition

4 out of 5
Americans support overturning the pharmacist "gag rule" (which was signed into law in October)

3 of 5
Americans support disclosing drug list prices in DTC ads

How Drug Distribution Works

A complex supply chain determines how prescription drugs are paid for in the U.S.



Putting Innovation in New Context

Healthcare has long invested in campaigns and ads focused on redefining value, specifically showing the kind of personal commitment and financial investment that goes into bringing a life-changing treatment or service to market.

Now, we're seeing leaders changing the context of healthcare innovation. Today, it's not just about improvement in care; it's invention in its highest form.

A recent survey conducted by pharmaceutical company Merck revealed that only 5 percent of respondents cited medicine as the next greatest invention. Merck responded with a striking "Inventing for Life" video that asked people what invention they couldn't wait for. The answers varied from a transparent toaster to a teleportation machine to canned sunshine to, of course, the biggest invention of all: a cure.

See the video

Success Scenarios

In this price-pressured environment, the question isn't really about hard costs; it's about value for those costs.

So it's no surprise that in 2019 interest in innovative and value-based contracting will remain high.

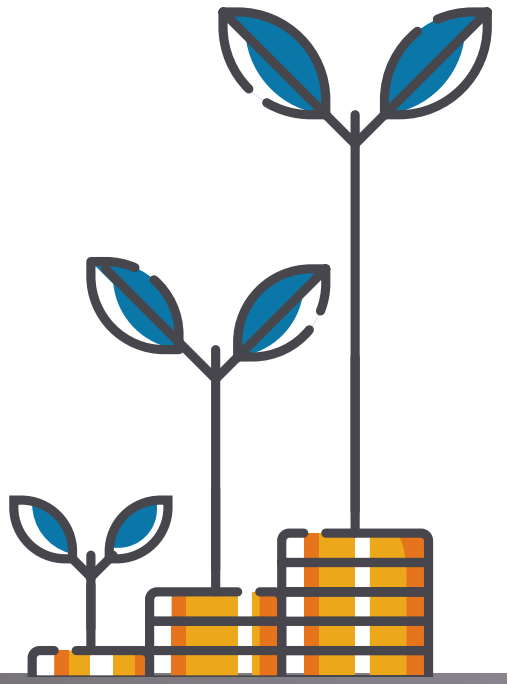
Today, the overall impact of outcomes-driven contracting remains rather small despite the widely publicized examples of early adopters. In all, there have been more than 200 innovative contracts publicly disclosed around the world. In the years ahead, pharmaceutical innovators will actively advocate for those contracts, leveraging real-world HEOR to demonstrate both the value and measurability of their drugs.

That advocacy will be critical because interest in value-based contracting significantly outpaces experience. In fact, a recent Academy of Managed Care Pharmacy (AMCP) survey of 128 payer executives[16] found that 68 percent would consider entering into an outcomes-based contract (OBC) with a manufacturer, but only one-third had experience with OBCs.

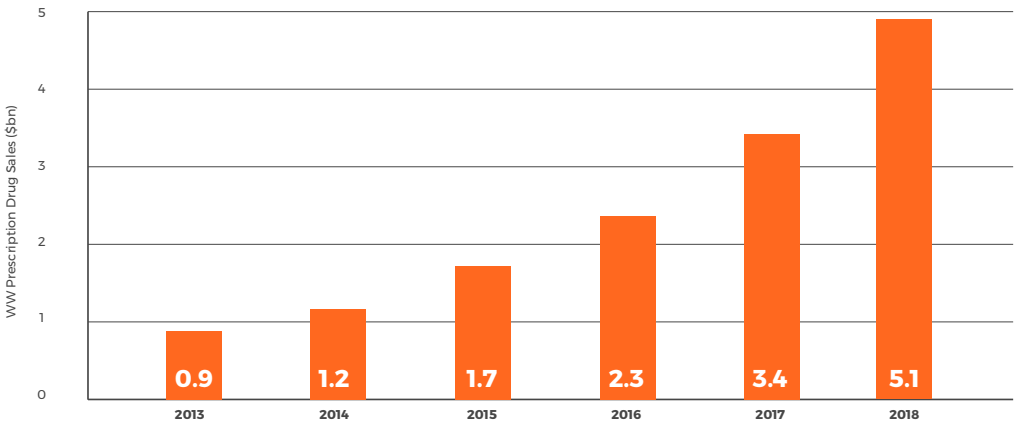
As manufacturers draft novel approaches to contracting, three strategic elements are becoming increasingly important:

1. **Well-defined endpoints** that provide clarity on both the relevant patient population and the specific clinical measure of success. Hepatitis C treatments are an example of a best-case scenario where both the patient and the measure (undetectable viral load) are clear and specific.
2. **Short-term impact** that increases the likelihood that a patient will be insured with the same payer and adherent over a commonly achievable time horizon.
3. **Collaborative data mining and operations** that unite payer and manufacturer in creating a single-minded value impact. For example, the Catalonia region in Spain has been a fast leader in executing innovative contracts because it invested early in health-monitoring tools, personal health identifiers to seamlessly link data sets and interoperability between medical record systems.

Today, value-based contracts largely pivot off of specific clinical test results. In 2020 and beyond, look for new contracts that sub-segment patients based on their technology adoption profiles, and track behavior and impact in real life via wearables and digital interventions. Specialized clinical research teams will include digital arms in Phase 3 and real-world studies that demonstrate the overall value that pill + digital support can provide, allowing value-based contracts to be written against solutions, not just therapeutics.



Average Number of Outcomes-Based Contracts



Future Ready

Questions and Discussion for Value Puzzle

Do we understand the new cost management levers in our category? How are those impacted by other co-morbid conditions our patients might be facing? What new evidence might help define our treatment's economic impact?

Have we appropriate war gamed potential legislation? What changes do we most need to be ready for?

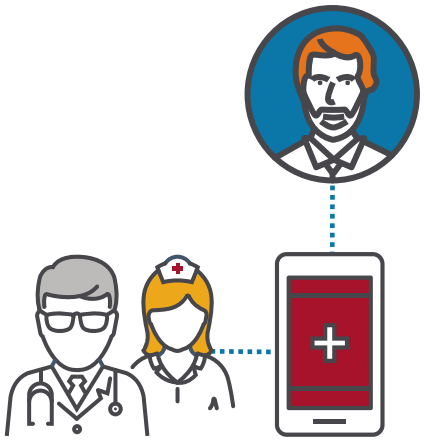
What value-based contracts will we likely be asked for? Do we have the strategic evidence in place? What value-based contracts will health systems and practices be asked for? Do we have the right evidence in place for them?

Have we prepared doctors to have meaningful conversations about price? How will the pressure PBMS are under affect us?

SYSTEM OF ONE

Care increasingly happens where health happens: at the clinic, at home, at local pharmacies and even on the phone. In 2019, the patient experience—from everyday health to clinical trial inclusion—will be more transient, opportunistic and data-connected.

System of One | Dynamics



Diagnosed Anywhere

With just a smartphone, you can test your lung function, heart health, urine and more. Increasingly sophisticated diagnostics are going to change conversations about care at home, within retail environments and in primary care.

(READ MORE ON PAGE 74)

Always-On Sensors

Frameworks, like Apple ResearchKit and Carekit, are libraries of code that allow researchers to create smartphone-based research studies easily. The sensors in smartphones make them powerful tools for gathering data about a person's well-being in their micro-environment.

(READ MORE ON PAGE 75)

Social Determinant Segmentation

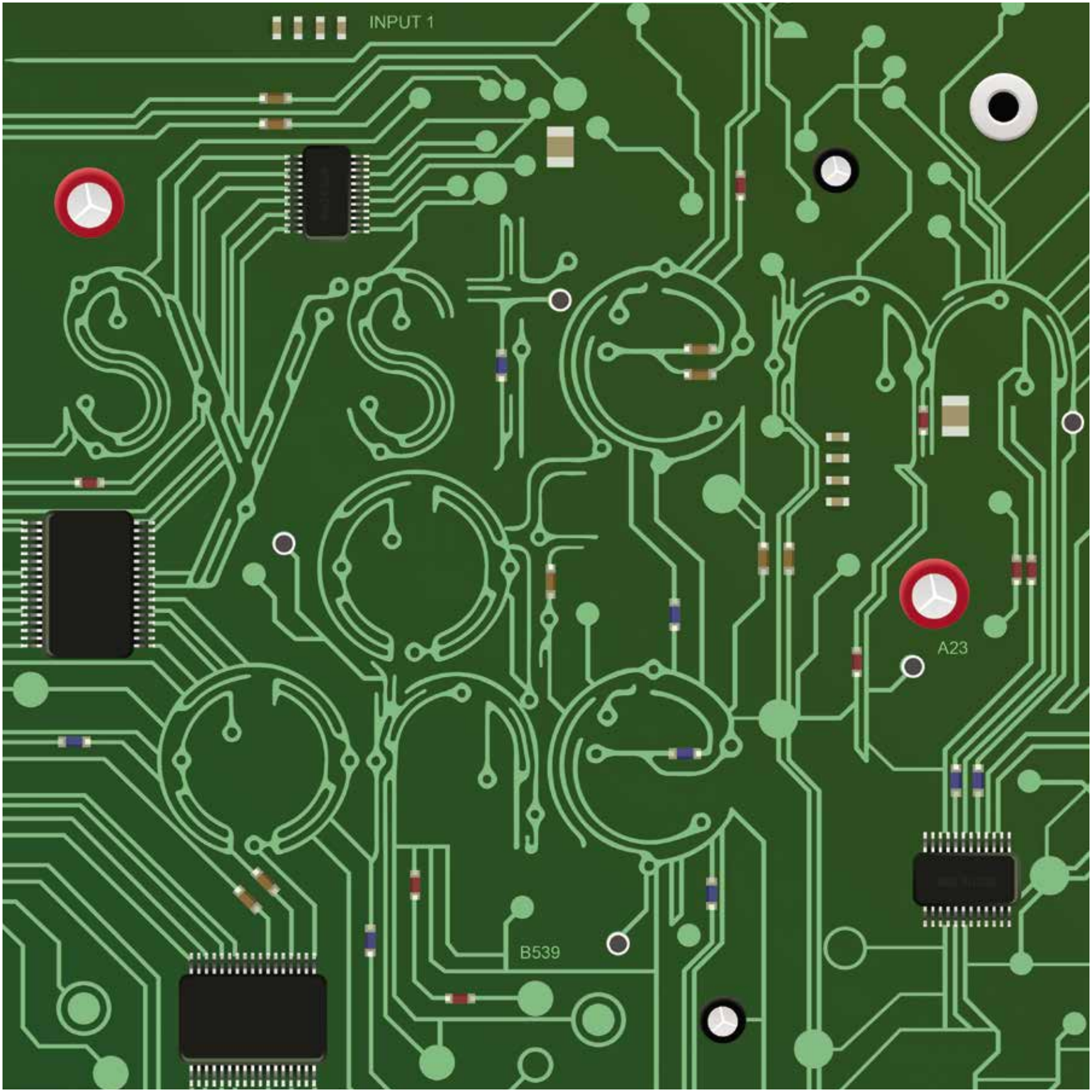
The Food and Drug Administration (FDA) and National Institute of Health (NIH) are unveiling new initiatives to understand social determinants of health in a way that adequately factors in America's diversity in terms of race, age, gender and socioeconomics.

(READ MORE ON PAGE 77)

Clinical Trials Everywhere

Instead of limiting their recruitment efforts to the people who live near a traditional research site, sponsors and innovators are looking through the full universe of patients who might respond to an everywhere, anywhere opportunity.

(READ MORE ON PAGE 79)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Diagnosed Anywhere

What's wrong? Increasingly, technology-driven tools can tell.

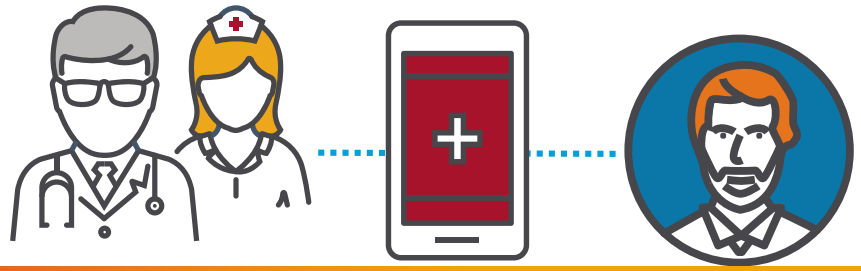
Around the globe, the cost and waiting game to see a doctor will drive growth and utilization of alternate diagnostic tools, at a moment when innovators large and small are uncovering almost unimaginable new possibilities for them. In 2019, look for increasingly sophisticated diagnostics to change conversations about care at home, within retail environments and at primary care.

What can you test at home with the help of your smartphone? Your lung function, heart health and urine, just to name a few. In 2018, the FDA approved the third smartphone-enabled home urine testing platform. The latest from inui Health can test protein, glucose, leukocyte, nitrite and ketone to show indications of everything from UTIs to diabetes to kidney function. Users instantly access their test results on their smartphones (presumably after washing their hands). AliveCor created an FDA-approved mobile EKG monitor that delivers a medical-grade electrocardiogram (ECG) to your smartphone in just 30 seconds. Air Next is a wireless home spirometer from NuvoAir that measures lung function and lets users track their lung health over time on their smartphones.

As front-of-store sales slow at drugstore giants, due to competition from both Amazon and low-price alternatives, increasingly robust healthcare clinics will fill in the footprint. Those distributed healthcare destinations will be powered by new diagnostic tools that help pharmacists act like disease detectives, not just dispensers and injectors. CVS is the in-store clinic leader in the U.S. with 1,000 MinuteClinics (compared to 400 similar retail health spaces at Walgreens)[30]. They're already testing vision and audiology services, active chronic disease care and diabetes management.

Meanwhile, anywhere-diagnosis tech is changing the work of primary care practices, too. Cognoa created a machine-learning app for pediatric behavioral health designed to reduce the time from an autism diagnosis to meaningful interventions. A primary care doctor can use the app with parents to capture information and videos of a child's natural behavior. The app then assesses the child's development to help the physician identify the best course of action.

In 2018, the FDA approved IDx-DR, the first autonomous, AI-based diagnostic system authorized for commercialization in the U.S. The system creates an immediate, reliable assessment for diabetic retinopathy, including macular edema, during a routine office visit in a primary care setting. The diagnostic report includes treatment advice aligned with the American Academy of Ophthalmology's preferred practice pattern for diabetic retinopathy. So, the doctor can counsel patients on recommended treatment next steps before they leave the office.



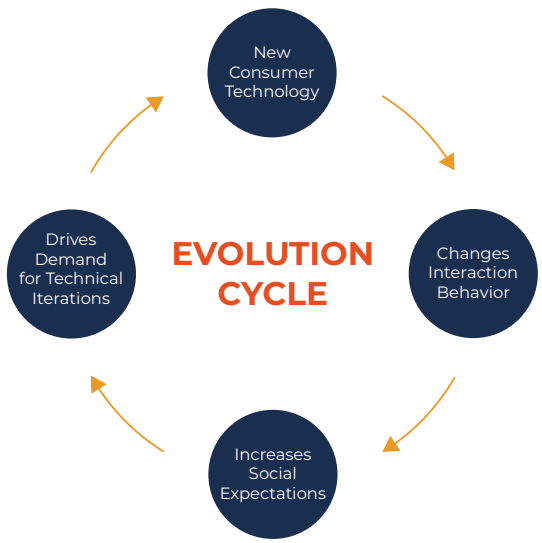
The Role of Consumer Technology in Healthcare Evolution

The tools we adopt in our everyday consumer lives drive an evolution cycle that ultimately changes healthcare expectations.

New technology leads to changing our behaviors. As we integrate this new tech, it both raises the bar for our collective social expectations and continues to drive demand for new advances.

We are in the midst of many parallel evolution cycles. One dynamic that arises from most of these cycles is the reinforcement of the expectation that we will have on-demand information readily available to us.

But newer ones are challenging the interface of health, too, including a growing expectation for voice-driven navigation, visual search and hyper-local customization.



Always-On Sensors

Smartphones continue to change and challenge nearly every aspect of how we think about daily health management.

Increasingly, they're also impacting how investigators and sponsors collect and analyze data.

The onboard sensors in smartphones make them powerful tools to gather data about a person's well-being in their micro-environment, and their processers allow them to turn complex sensor data into healthcare meaning—right on the device.

Bluetooth allows smartphones to tap into a fast-growing internet of medical things to capture even more robust and specialized data from external devices. The FCC saw this as so important that they set aside certain frequencies in the wireless spectrum to be designated as the medical body area network.

Increasingly, clinical teams are writing algorithms that take advantage of native machine learning to generate advanced healthcare data. Much of that data is gathered and crunched passively without requiring input from the user. Notifications are leveraged to engage the user only when necessary to gather patient-reported information.

Constant internet connections allow us to gather contextual insights. Much of this data can be captured passively to help provide greater understanding of some of the factors related to social determinants of health, like air-quality index, water-quality index, CDC data and socioeconomic data.

What's supercharging the pharmaceutical industry's use of smartphone data collection in 2019: frameworks like Apple ResearchKit and Carekit. Such frameworks are libraries of modular code that allow researchers to create smartphone-based research studies with little effort.

At their initial launch, studies leveraging the frameworks were largely investigator- or advocacy-led. Today, the frameworks are on their second major release, and pharmaceutical leaders around the world are seeing what more they can learn with a smartphone. In 2018, Novartis launched FocalView, an ophthalmic app created with Apple ResearchKit to modernize clinical trials in ophthalmology. It administers eye tests, tracks activity (independence) and asks users questions on mood and wellness. GSK was the first pharmaceutical leader to adopt the frameworks with its 2016-2017 PARADE study.[12]

In 2019 and beyond, we'll see more of a focus on how people and investigators use that data. The new expectation will be for actionable, newsfeed-style data scrolls, comparative data and natural language query, potentially via voice search.

Environmental
micro

Barometric Pressure
Altitude
Humidity
Ambient Light

Motion

Accelerometer
Gyroscope
Proximity

Location
macro/micro

GPS
Compass
Beacon

Processing

Motion Processing
Neural Engine
Machine Learning

The Power of Branding in Unconventional Clinical Trials: Cloudy with a Chance of Pain

Cloudy with a Chance of Pain is the world's first smartphone-based study to investigate the association between weather and chronic pain.

Cloudy with a Chance of Pain was branded for and designed around the patient experience as a key driver of *consumer perception*. It was featured on BBC Two's "Trust Me, I'm a Doctor" and BBC One's "Breakfast" to help drive awareness and measure the *effect of that perception*. Potential participants were directed to the study website www.cloudywithachanceofpain.com to enroll, thereby providing a direct way to measure the *value of the perception effect*.[34]

RA-specific items

1. Pain severity
"How severe was your pain today?"

2. Fatigue
"How severe was your fatigue today?"

3. Tiredness on waking
"How tired did you feel when you awoke this morning?"

4. Morning stiffness
"How stiff did you feel on waking this morning?"

5. Well-being
"How well did you feel today?"

6. Overall disease severity
"How severe has your R.A. been today?"

Non RA-specific items

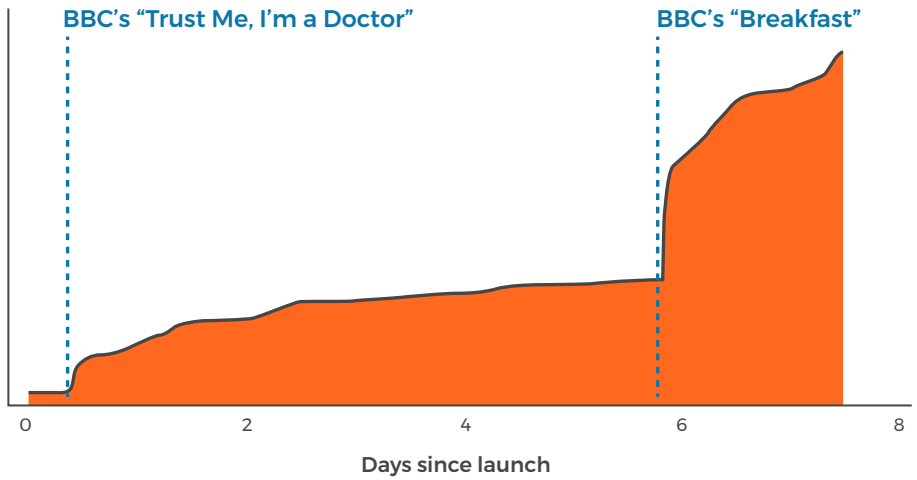
7. Mood
"How has your mood been today?"

8. Physical activity
"How long have you exercised today?"

9. Time spent outside
"How much time have you spent outside today?"

10. Perceived influence of weather
"How much has the weather influenced your pain today?"

Cumulative Enrollment in 1st Week



Results

84,494 visits from 22,732 visitors

22,046 views of the "Take Part" page

18,631 completed eligibility questionnaires

15,836 were determined eligible

5,683 participants successfully enrolled

Social Determinant Segmentation

Healthcare brands are discovering the power and relevance of social and economic segmentation to create services and support that help dismantle barriers, level disparities and increase access to care.

In 2019, we'll see an increased focus on social determinants of health. Historically, the levers we've had to understand those social and behavioral factors beyond geography have been limited to income, education and race. Those insights were based on huge public health datasets that generated observations that, while compelling in the macro, are generally not actionable in a 30-minute clinic visit. Several things are set to change that in the years ahead.

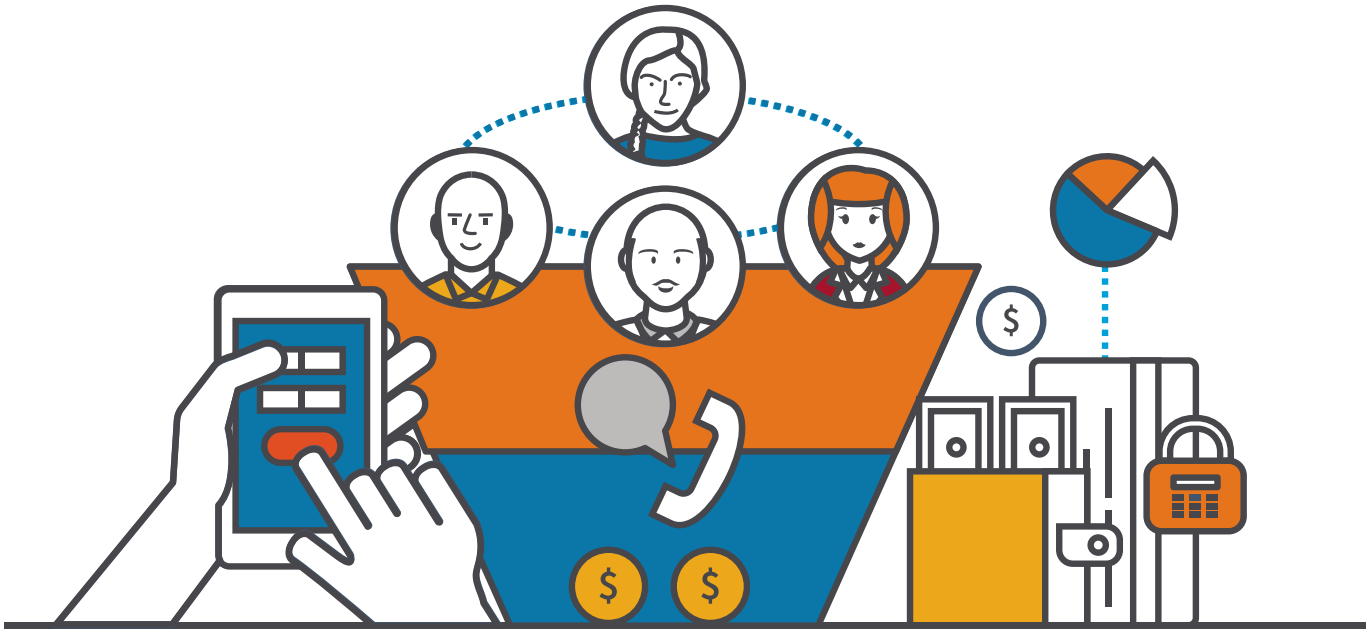
One of the goals of the 21st Century Cures Act in the U.S. is to understand how education level, socioeconomic status and other social determinants affect health outcomes for underserved populations. Speaking before a House committee in late July 2018, leaders of both the NIH and the FDA emphasized that all data-gathering under the Cures Act must take stock of multiple populations.

Through an initiative called "All of Us," the NIH is enrolling one million American volunteers in the equivalent of a crowd-sourced biomedical data repository. Pooling information from EHRs, blood samples, records of environmental exposures, and culture and behavior patterns, the program will create the first-ever research database that truly reflects the nation's diversity in terms of race, age, gender and socioeconomics. The database is designed intentionally to oversample minority communities that, until now, have been underrepresented in biomedical research.

China has invested in a decade-long effort to decrease healthcare inequity and is measuring social determinants, like income and education level, to measure the plan's impact. Canada has long been seen as a leader in social determinants of health research and the Federal Minister of Health has set acting on social determinants insight as a priority for the government.

These new insights can have profound, positive implications for pharmaceutical innovators.

However, along with opportunities, the trend also brings new imperatives. In the past, pharmaceutical marketers might be content if a disease awareness campaign spurred patients to talk with their doctors. This no longer hits the mark. Today, in a best-case scenario, that marketing group would work across company silos with partners in clinical and market-access divisions to identify the needs of underserved populations and craft innovative initiatives to help.[39]



New Questions for the Social Determinants of Health (SDH) Action Era

- Can the initiative help level the playing field by ensuring everyone is speaking the same language? Perhaps the program can help shore up health literacy of the target populations.
- Does the initiative bring diverse patient voices to the table and/or promote diversity research? When engaging racially or ethnically diverse groups, could you also run an education program that will lead to more diverse enrollment in your clinical trials—and explain to stakeholders why that's important?
- Does the product or recruitment campaign help restrain drivers of mistrust that keep vulnerable populations from engaging in the healthcare system? Can we partner with businesses that enjoy the trust of local communities to draw people in?
- Have we applied the best principles of behavioral science in terms of promoting behavior that's associated with good health outcomes—as opposed to simply emphasizing the importance of medication adherence?
- Have we had enough internal conversations about what multicultural marketing means before we take the product to the market? (Hint: It's not just about translating label information on a Facebook page or hiring multiracial actors in a TV ad.)

Clinical Trials Everywhere

The barriers to increased clinical trial participation once seemed insurmountable.

How could we overcome huge gaps in geography, transportation, awareness and trust? In 2019, there's a new paradigm in clinical research that's doing just that: by letting patients receive care closer to home in an environment they already know and trust.

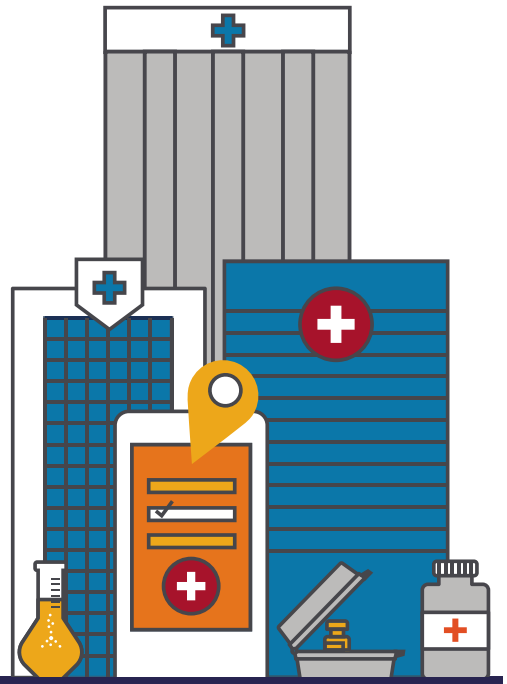
Sponsors and innovators are expanding their view. Instead of limiting their search to traditional research sites with the full infrastructure and staff to manage a trial, they're looking into every practice. That's expanding their reach, too, from the ~3 percent of people who live near a research site and can be recruited through traditional and social media, to the full universe of patients who might respond to an everywhere, anywhere opportunity.

EHR will become a critical mechanism of site identification in 2019. In EHR, study criteria like therapeutic specialty, patient pool demographics and geographic location can point to practices likely to have patients who would qualify for the study. Although many of the practices located won't be traditional research sites, new centralized teams and infrastructure are making it possible for sponsors to work with any physician, keeping the patient in the local practice and permitting the trial to be administered across significant geographies.

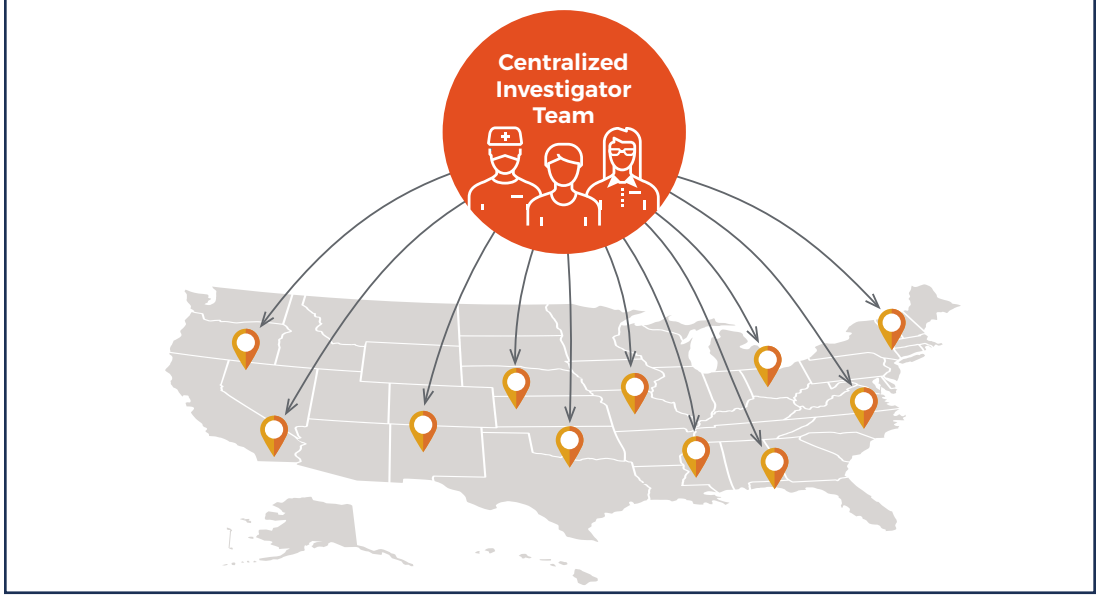
The centralized teams serve as the research associates and investigators. They provide training and regulatory guidance, and can deploy experts as needed. The local doctor offers the trial opportunity to relevant patients, monitors their overall care and stays connected to the central research team.

In the years ahead, look for more "third place" options for patients that might include the ability to receive clinical trial tests, administration or other interactions at their local pharmacy, clinic or even at home. Additionally, there will be more "no place" trials, which directly mine live or retrospective data from electronic health records to track patient response.

In addition to time and cost savings, early movers are looking to these new approaches to meet the call of advocates and regulators around the world: bring more clinical research to underrepresented populations in community settings that look more like a real-world environment.



The New Trial Footprint



Future Ready

Questions and Discussion for System of One

Have we updated our patient journeys and intervention plans to reflect all the places a patient might receive a diagnosis or ongoing care? What new at-home diagnostics could potentially be in the patient consideration set over the next one to three years?

Can our trials be more efficient with some centralized teams? Are there areas where physical sites are limited or difficult to access that we could augment with non-traditional research sites?

What non-clinical data would make our evidence package more compelling? Is there anything new we could gather via smartphone-included clinical trials?

Have we activated understandings of social determinants of health in our clinical and commercial strategies? Are we supporting people in ways that help them achieve success in treatment?

THE NEW TOP TALENT

Massive shifts in the expectations of customers and the reality of healthcare are driving demand for talent ready to excel in this new era. Companies are retooling, rethinking and recruiting for 2019.

The New Top Talent | Dynamics

High Tech + High Touch

There will be evolved expectations for clinical site managers, educators, marketers and sales reps, on account of the demand for hybrid professionals that can work with data as comfortably as they can perform real-life engagements.

(READ MORE ON PAGE 84)

The Arms Race for Talent

In their searches for talent, companies are increasingly talking about a hybrid model of upskilling and hiring. With customized immersive training, they're treating both new hires and hand-picked current employees like apprentices, to fast track the development of über-experts.

(READ MORE ON PAGE 85)

New Challenge: Talent Mix

Ditching siloed advertising efforts, companies will use digital to change their interactions with consumers from the ground up. Manufacturers will rebalance teams to answer new market needs and competitive context.

(READ MORE ON PAGE 86)

The New Bar: Performance

In an industry trending toward more outsourcing, new performance-based contracts are a powerful response to risk and uncertainty in aggressively cost-controlled launches.

(READ MORE ON PAGE 87)

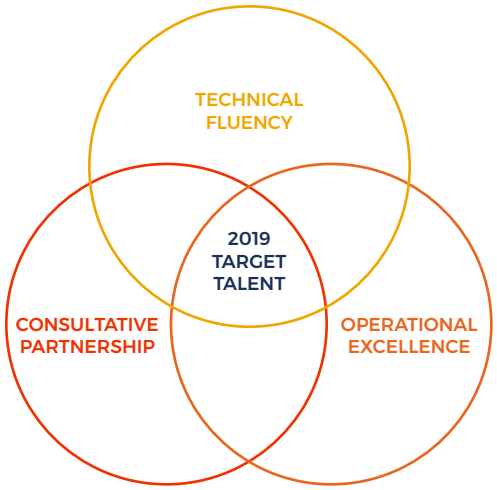

NEW TOP
Talent
CHOOSE WISELY
Enjoy!
COIN

High Tech + High Touch

If there's one universal across nearly every aspect of life sciences talent strategy going into 2019, it's the need for hybrid talent who is as fluent in data as they are in real-life engagement.

This high-demand talent set can access, translate and take action on data in one moment and have a consultative and powerful conversation with a critical stakeholder the next, all while maintaining operational excellence and efficiency.

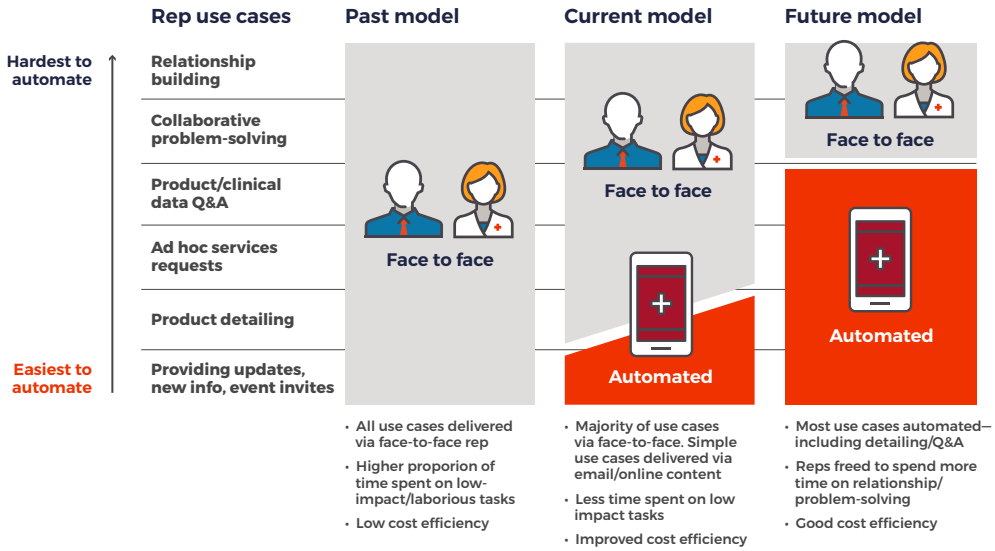
That role looks different across the clinical-commercial spectrum but has those three pillars of ability in common. For example:



- **The new clinical site manager:** In 2019, the most successful clinical managers will earn loyalty through tailored site engagements. They'll be ready to take on more consultative roles, working with site leaders to establish the right internal processes and co-create recruitment approaches. They will proactively bring investigator insights back to the sponsor to continue to improve experience over time.
- **The new clinical educator:** The 2019 talent differentiator will be in command of anywhere/everywhere technology. Nurses and other medical experts will be as comfortable educating and engaging patients or office staff on video, email and chat as they are in person. They should effortlessly manage asynchronous communications to encourage and support over time.
- **The new marketer:** In the coming year, the new expectations all center around the ability to engage with, understand and act on data. Leaders are looking for massive organizational rewiring that will bring more data fluency into every aspect of communications and marketing.
- **The new sales rep:** The field force is changing rapidly, and increasingly, new talent will either be a super specialist—deep in reimbursement, clinical application or patient support—or a hybrid who can effectively navigate every aspect of education and support. These reps are expected to be able to leverage technology to communicate with practices, deepen their skills and learn from their peers through dynamic recommendations and insights.

What the High Tech + High Touch Evolution Looks Like

For the field force, as an example, technology isn't expected to replace highly effective talent. Instead, it will supplement them and change and evolve where they can have the most impact.



The Arms Race for Talent

In 2019, healthcare leaders are increasingly asking: *Where do we find the talent we need?*

Employment markets around the world—especially in the U.S. and China—are more compressed than ever. Quit rates are at the highest in decades. Availability of right-fit talent is at its lowest.

Leaders are deciding: *Do we upskill or do we hire?*

Upskilling has its challenges going into 2019 as top internal talent is limited by the buyouts, layoffs and other rightsizing of recent years. Many junior team members are eager but have multiple dimensions of growth to invest in.

Hiring is made difficult by the complexity of the environment and the products we're working with today. New team members have to be near-experts from Day One, plus ready and able to cut through the complexity with clarity.

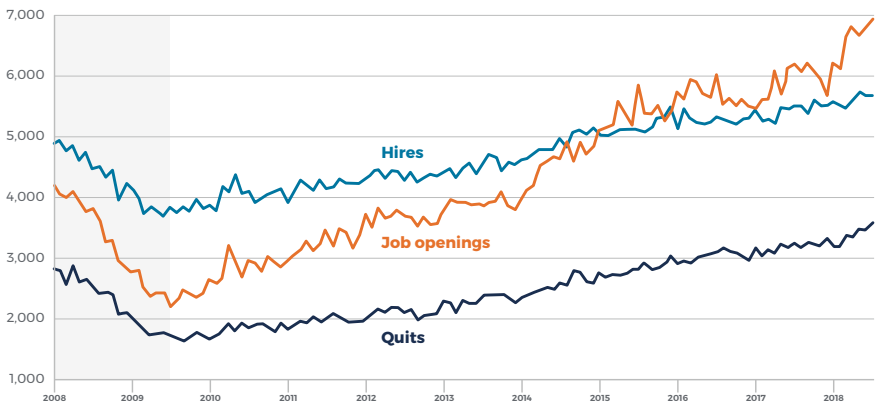
Companies are increasingly talking about a hybrid model that customizes immersive training to both the company's products and customer support philosophy. This full-focus approach treats both new hires and handpicked current employees like apprentices to fast-track the development of über-experts who model both knowledge and approach for their peers. In 2019, programs like this will flourish both internally and with partnered and outsourced teams.

The Real Math

Hiring is at All-Time High and not Keeping Pace with Openings, Meanwhile Quit Rates Double Since 2008

The U.S. Bureau of Labor Statistics[28] pegged unemployment at just **4.1 percent** at the time of writing this report. Unemployment among people with a bachelor's degree and sales experience is even lower: **~2 percent**. Add in therapeutic category—or even broad healthcare—history and you can imagine how the number drops to nearly nothing. That limited talent supply has fueled one of the highest quit rates in recent decades and a continuous uptick of compensation in our category that outpaces the national average.

Note: Shaded area represents recession as determined by the National Bureau of Economic Research (NBER).



New Challenge: Talent Mix

In 2019, companies will focus on a new commercial talent mix to spur holistic digital transformation. They'll use digital to change their interactions with healthcare stakeholders from the ground up.

Manufacturers are rebalancing teams to answer new market needs and competitive context. They will tackle the inevitable friction of introducing new roles and managing change head-on with agile processes that let disparate teams co-create and innovate together. Here's what that might look like:

At the home office: Marketing strategist + data scientists

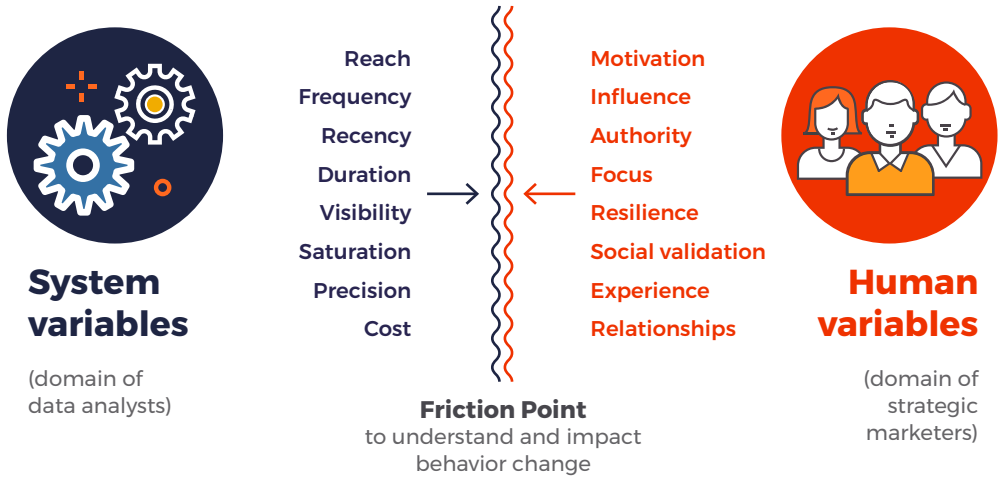
Leaders are bringing together two sides of human understanding to impact behavior change in new ways. The marketers bring a deep understanding of motivations, perspective and creativity; the data scientists lean in with analysis, evaluation and prediction.

In sprint-speed projects, these teams are able to quickly learn from each other, build new hypotheses and break down silos to create lasting ways of work.

In the field: Front-line field leaders + integrated commercial teams

Today's frontline leaders have an entirely new challenge: how to integrate and activate complex teams that include everything from contact centers to clinical specialists to reimbursement experts and more.

They're actively rebalancing resource mixes in real time while cross-training to support more efficient hybrid roles over time. These leaders are looking for a constant feedback loop from both their specialists and practices to be able to create the most relevant mix of talent for their diverse region.



Digital Expectation at GSK

To drive change and transformation in marketing, GSK relaunched its marketing capability program, called Marketing iQ. It's teaching new skills in building trusted brands as well as much deeper digital iQ.

At GSK, digital isn't "digital marketing." **It's marketing in a digital world**. In the past, they told marketers to spend 20 percent of their budget on digital. But people didn't know how. The result was a lot of unproductive spend in display advertising.

Today, they're creating a safe environment to learn digital. It's absolutely OK not to know how to market in a digital world, Mark Speaker, chief digital officer at GSK, explained, as long as you raise your hand and ask for help. It's just not OK to sit in silence.

Transformation doesn't stop with marketing. According to Speaker, GSK is leading a new era of change that partners with technology, R&D and others to build a true digital innovation hub that creates integrated solutions to serve consumers in new ways.[9]

The New Bar: Performance

When it comes to outsourced commercial talent, healthcare leaders are increasingly thinking about risk-based models that best leverage operations and skill sets on both sides.

In these new contracts, partners move from fee-for-service engagements to performance-based incentives, much like the broader healthcare industry.

In 2019, that's increasingly important because the industry is trending toward more outsourcing, in large part due to moderate risk and uncertainty in aggressively cost-controlled launches. These new contracts tend to be more horizontal, aggregating teams across commercial silos, giving partners a clearer view to accurately estimate performance and the resources and strategies needed to achieve it.

Over the year ahead, balanced contracting schemas will get more sophisticated, showing exactly what strategic levers need to be agreed upon to design results-based contracts. Look for sharper definitions around return on spend, workforce resourcing and market simulation, as well as lead and laggard tools to ensure transparency.

Traditional support contract

Command and control

Input and processes

Price

Outcome-based contract

Collaboration

Output and results

Value

Future Ready

Questions and Discussion for New Top Talent

Are our teams able to both leverage the newest technology and build powerful relationships with providers and patients?

Should we upskill or should we hire?

Do we have strategies in place to integrate teams that complement each other but may not have shared history/fluency?

Do we have strategic contracting in place to be able to co-invest in outcomes-based programs that position both partners for success?

Methodology

The 2019 Health Trend Ten represents the knowledge and experience of more than 200 leaders and experts who work on the front lines of healthcare. Through research, interviews and workshops, we're able to triangulate a future-facing look at the challenges and opportunities ahead.

Report Authors

Lead Author:
Leigh Householder

Executive Committee:

Lisa Arbogast
Janet Baldwin
Sebastian Bather
Howard Brock
Heather Campbell
Jemma Contreras
Dan Cummings
Bryan Distefano
Mike Ford
Joel Gerber
Audrey Gilfor
Rich Gorman
Clare Grace
Tim Haas
Dave Hewitt
Leigh Householder
Amy Hutnik
Shusei Ichikawa
Nitya Kamalanathan
Bryan Katz
Michelle Keefe
Keith Kelly
Nick Kenny
Mike Kleppinger
Kevin Kohl
Patrick Leary
Ryan Maglione
Kellie Malloy Foerter
Nick Marasco
John McCormick
Mike McDevitt
Paul Mignon
Keith Morris
Paige Nelson
Judith Ng-Cashin
Dannelle Palmer
Neel Patel
Miranda Porter
Dave Querry
Suma Ramadas
Vijay Rao
Patrick Richard
Andrew Rosner
Baba Shetty
Rohit Sood
Nick Spittal
Rachel Stahler
Kathleen Starr
Adam Steadman
Lisa Stockman
Lee Taurman
David Thompson
Mike Tilton
Christian Tucat
Ilya Vedrashko
Manfred Weiler
Alexandria Wise-Rankovic

Contributors:

Ben Abramowitz
Lauren Ankeles
Meg Alexander
Carol Aliyar
Kristen Ambegaokar
Daniella Apolonia
Duncan Arbour
Nicole Aronson
Michael Austin
Nelson Azoulay
Catie Ball
Wendy Balter
Chris Bedell
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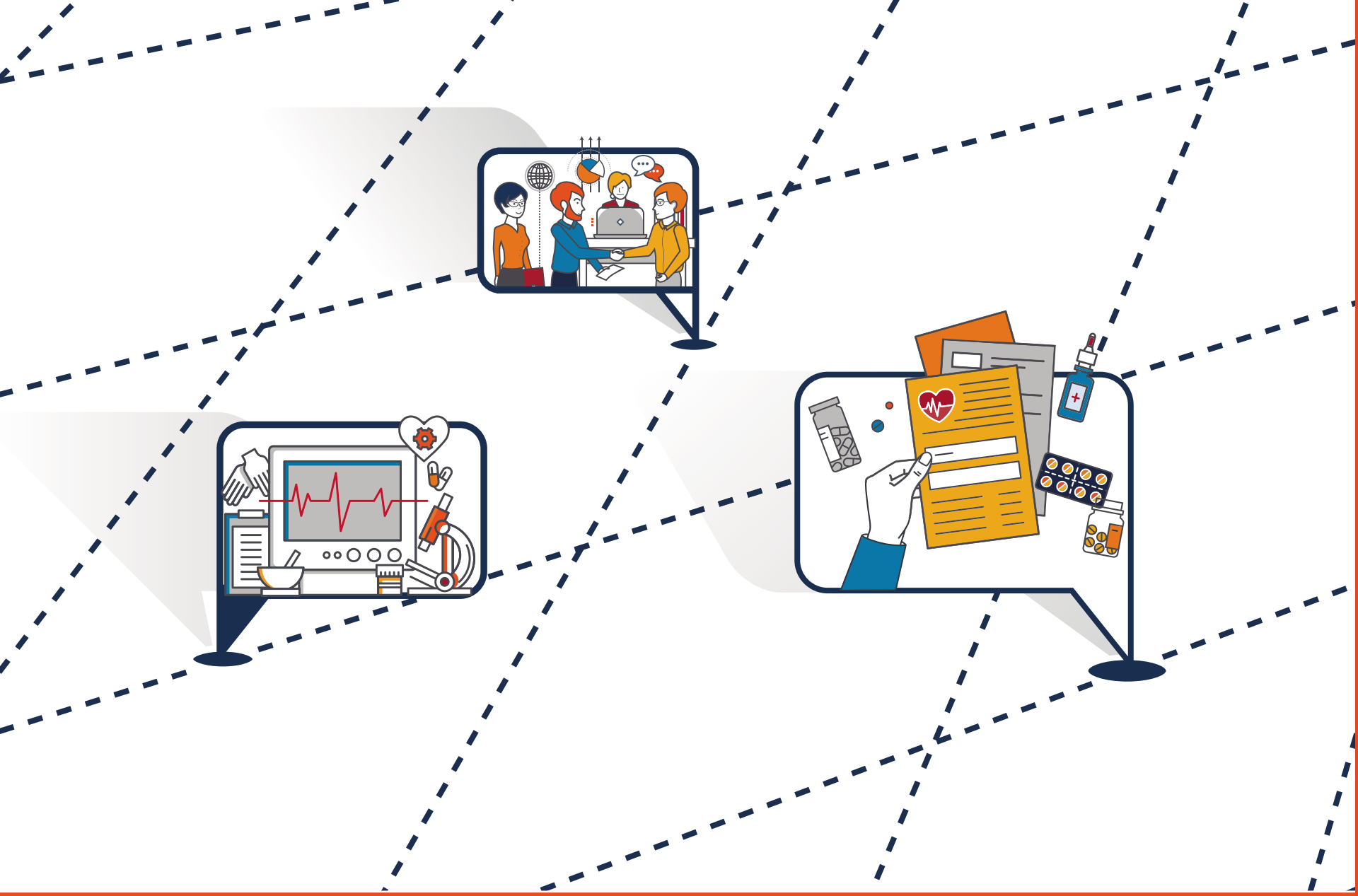

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