



**Life sciences 2025 –  
managing disruptions  
to gain competitive  
advantage**

**Driving risks to results**



**EY**

Building a better  
working world

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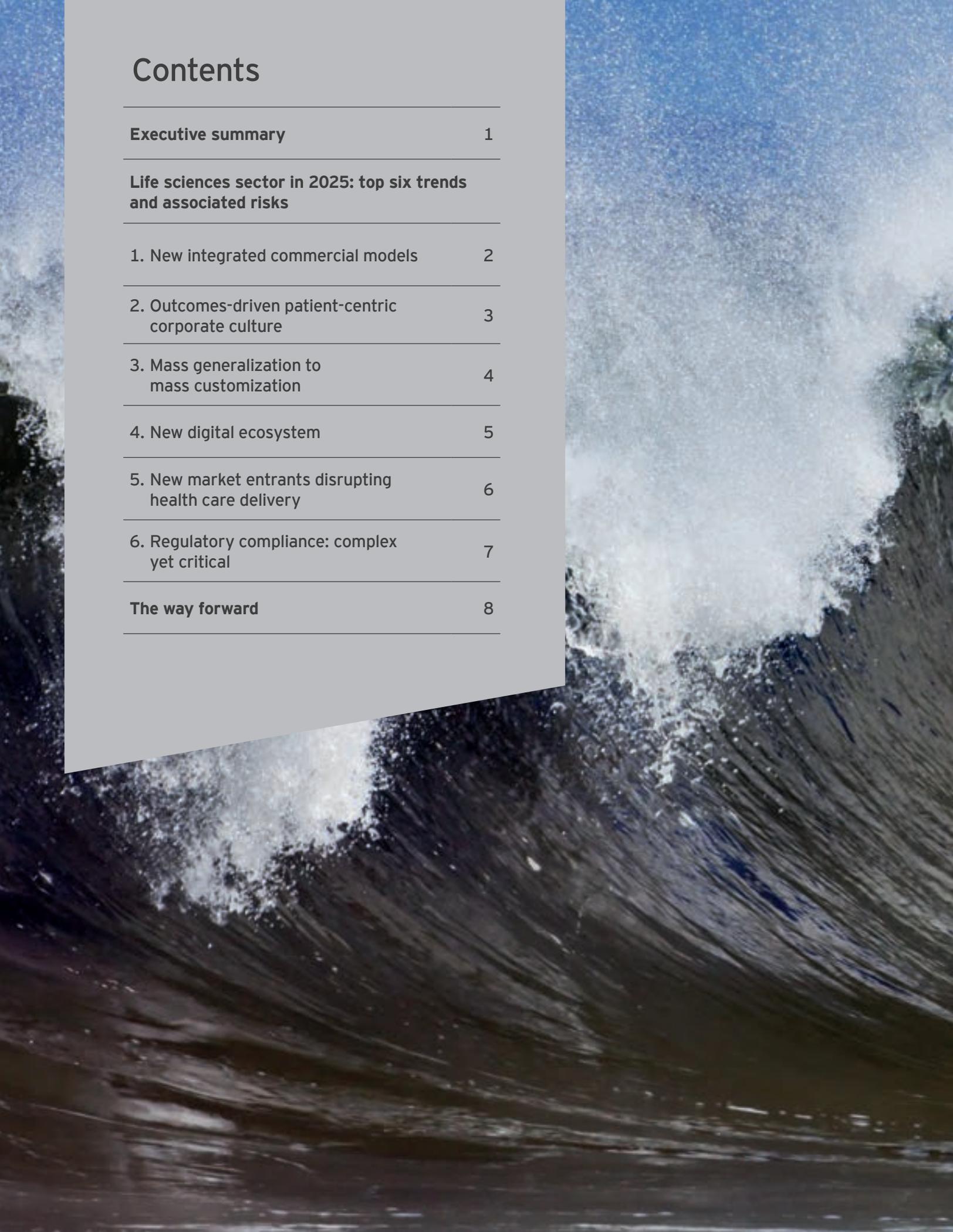
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# Executive summary

We have entered an era of profound transformation in life sciences. The landscape is changing rapidly, and what holds true today could be drastically altered or may not even exist tomorrow. Dealing with – and thriving within – this era of continuous change requires regular, robust and well-organized risk assessment and prioritization.

Life sciences companies are facing unprecedented change. Their customers are changing, the nature of their products and sales models are changing, and they face new kinds of competitors. Budgetary pressures are impacting health care systems globally, payers are pushing back aggressively on prices and demanding evidence of value, and digitally empowered and increasingly informed patients are playing a more active role in their treatment.

EY projects that by 2025, many life sciences companies will have transitioned toward more patient-centric business models, offering products and services designed to improve outcomes and address the specific needs of empowered consumers. The market will be characterized by mass customization, enabled by continuous technological advancements and a host of new health care players.

## Old reality 2005

Push branded products to patients

Value creation from sales of branded pharmaceuticals
Corporate culture focused on maximizing drug sales volume and price
Mass generalization: focus on blockbuster drugs with low/no technology usage
IT infrastructure as process enabler
High pricing power through size, global infrastructure and branding
Regulatory and compliance requirements limited mainly to drug safety and efficacy



## New reality 2025

Chase outcome-based health solutions and satisfy the empowered health consumer

<b>New commercial model (integrated system)</b> Integrated global health care (HC) provider create value along the health care delivery continuum by offering therapeutic and preventive solutions.
<b>Outcome-driven, patient-centric corporate culture</b> Evolution toward a flatter corporate culture is focused on achieving profitability through enhancing patient outcomes.
<b>Mass generalization to mass customization</b> Technology, innovation and network-based R&D incubate outcome-based and patient-centric health solutions, comprising not only drugs but also support services and technologies.
<b>New digital ecosystem</b> Technological, data-driven advances are building a new digital ecosystem and delivering new kinds of value.
<b>New market entrants disrupting health care delivery</b> Pharma's competitive positioning and pricing power will be challenged by new, fast-moving market entrants and by the expectations of empowered consumers.
<b>Regulatory compliance: complex yet critical</b> Regulatory compliance will be more complex, yet critical to gaining competitive advantage and building trust.

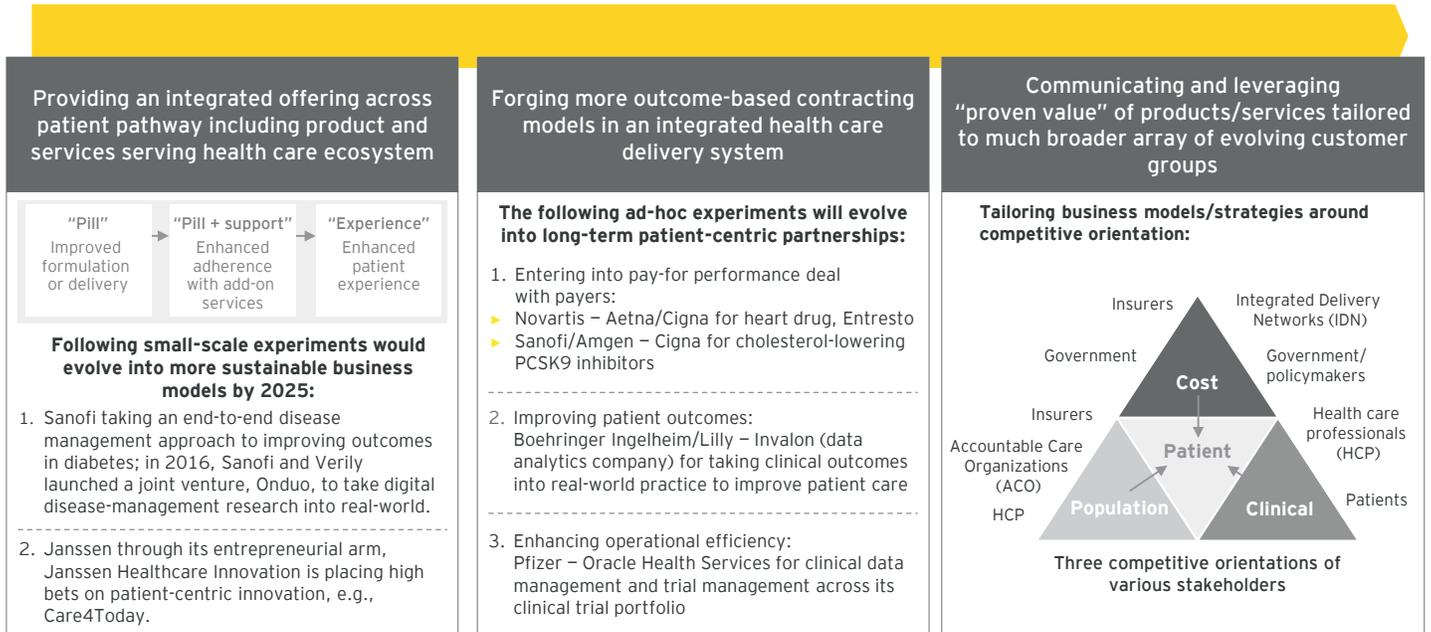
This shift will require cultural, organizational and strategic change. It will present multiple new, unfamiliar challenges and new kinds of risk. Identifying, assessing and managing these risks will be increasingly important for life sciences companies – not only to survive, but also to convert these risks

into opportunities to gain competitive edge in an increasingly dynamic, crowded and fast-changing sector. Turning the risks to results will require companies to identify these risks, assess their severity and probability, and be prepared to implement an appropriate risk response.

# 1 | New integrated commercial models

EY projects that by 2025, many life sciences organizations will have grown into integrated health care providers – offering both products and services and forging patient-centric contracts.

## New commercial model Evolution toward integrated health care providers



The increasing quest of a diverse group of stakeholders for “proven value” over “potential value” will compel life sciences companies to build “around-the-pill” health care solutions – blending drugs with differentiated patient services to deliver better health outcomes. This will involve more outcome-based contracting models with a wide range of payer and provider

organizations, many with different priorities and budgetary constraints. Though companies have started providing these kinds of services, they have most often been developed in a pilot fashion. Such small-scale random experiments would eventually turn into sustainable business models by 2025 with a comprehensive service strategy.

## Strategic risks to manage during the journey to building new commercial models

**Achieving the requisite ROI from value-added services:** demonstrating the value of – and thus being paid for – “around-the-pill” services offered to patients will be critical to biopharma profitability.

**Critically re-evaluating risk appetite and risk tolerance in the context of long-term strategy of “where to focus and play”:** risk should be embedded in rhythm of business to weigh your long-term strategy and plans to prepare for portfolios including services, solutions or even digital therapeutics. Continuously monitoring R&D investment decisions based on ROI and building appropriate “gating” mechanisms will play a critical role.

**Managing an uncertain geopolitical climate:** the global geopolitical landscape may look very different and more volatile, affecting organizations’ growth and investment decisions. For instance, repealing Obamacare could impact profit margins and accelerate the need for ongoing innovation.

**Complying with continually evolving – and expanding – legal and regulatory imperatives:** as biopharma products evolve into services and include increasing technological and data-driven components, legal and regulatory compliance obligations will multiply.

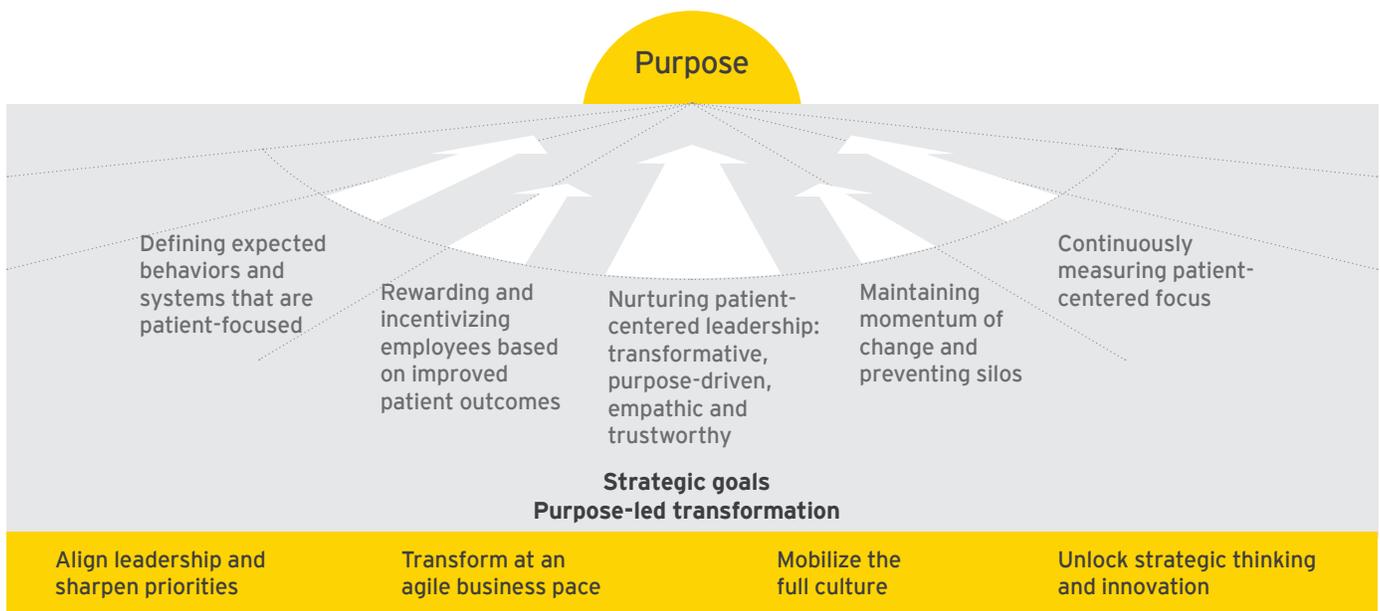
## 2 | Outcomes-driven, patient-centric corporate culture

EY projects that by 2025, an outcomes-driven, patient-centric corporate culture will be the new normal, guiding strategy, brand and leadership aligned to making a difference to patients.

EY projects that by 2025, patient-centricity will have evolved from buzzword to defining organizations' thoughts, beliefs and actions. The critical enabler will have been transformational, inspirational leaders, but also highly involved employees helping make that change permanent. Patient-centric organizations will have empowered their people with a sense of a common purpose and will be incentivizing them based on improved patient outcomes. Front-facing employees will reflect

a patient-centric culture in their communications with the external world. Continuing to hire new talent with shared values will be critical, alongside continual assessment of the patient-centric values within organizations. Though value propositions, organizational structures and profit formulas will differ from company to company, all will be purpose-driven and open toward new technologies and partnerships.

### Sector players will evolve toward a more outcomes-driven, patient-centric corporate culture



### Strategic risks to manage during the journey to embedding patient-centric culture

**Managing cultural change to define and sustain patient-centricity, and ensuring it translates into behaviors:** leadership must help drive a patient-centric culture, ensuring that people are recognized for patient-centric behaviors. Cultural change is a much longer process than just laying down policies and governance structures – it requires continuous monitoring and reinforcement.

**Linking patient value and shareholder value:** defining appropriate and measurable drivers that align patient value to shareholder value and managing the risks in achieving that alignment will be important.

**Enabling patients' voices to be heard:** ensuring that the end-to-end structures and processes are in place to enable patients' voices to be heard, translated into action and enabled to influence the organization is critical.

**Attracting and retaining appropriate talent and skills:** developing and providing patient-centric services and support, often technology-enabled, means biopharma will have to create new roles, build new knowledge, and attract and retain new kinds of experts.

### 3 | Mass generalization to mass customization

EY projects that 2025 will be an era of mass customization in care delivery, meeting consumers' needs in a more personalized fashion.

EY projects that by 2025, advances in wearables; sensing technologies; data analytics and machine learning; security and privacy protocols; and medical practices will have profoundly changed health care delivery. Patient care will be personalized – the drugs, solutions and services they receive, their experiences, their interactions with health care professionals/stakeholders, and even where they receive their care. Therapies will be more precisely tailored to each individual's needs, whether at a molecular level or via appropriately designed disease management support services. Data analytics will enable

real-time changes in patients' health status to be identified and addressed. Patients will be active partners in managing their own care, using a range of technologies, tools and incentives. They will be supported by personalized care plans from virtual advisors, created using machine learning technology. Virtual clinics will offer long-term monitoring of patients in their homes via patient-reported outcome tools. Homes will have replaced hospitals and physicians' offices as the main health care delivery hub. Health care will be available anywhere, anytime.

#### Mass generalization to mass customization

Patient pathway	Future scenarios	Precedents	Precedents	Future scenarios	Place of care delivery
Prevention	Patients will be active partners in managing their own care, using a range of technologies, tools and incentives.	iTBra is a comfortable, discreet intelligent insert allowing women to conduct monthly breast self-examination.	Rush University Medical Center partnered with a technology company (Tempus) to provide customized care to cancer patients using analytics and machine learning platforms.	Analytics would empower physicians to prepare distinct personalized care plans.	Hospitals/ACOs
Diagnosis	Personalized diagnostics (biomarkers, companion diagnostics) would match patients to the most appropriate treatment.	Owlstone Medical is adapting its existing disease breathalyzer technology, STRATA, to stratify asthma patients, matching them to the right treatment the first time.	Centers for Medicare and Medicaid Services has piloted a value-based reimbursement (VBR) program for the home health care industry.	Delivering care where patient is. Home would become the "health care center of the future."	Medical home
Treatment	Therapies will be more precisely tailored to each individual's needs.	Memorial Sloan Kettering has guided personalized cancer treatment for 10,000 patients using a power genetic sequencing test (MSK-IMPACT).	CardioPad enables quick cardiac examinations at rural locations and wireless image transfer to specialists for interpretations.	Evolution of IoT and mobility would take health care anywhere, anytime, even in rural areas.	Health care anywhere
Follow-up	Cognitive computing and predictive analytics would offer users contextual and individual advice.	In 2017, Welltok expanded partnership with IBM Watson to create a data-driven, personalized and engaging experience for individuals.			
Technologies (big data, genomic, wearables, sensors, CDx) and network-based R&D will incubate those trends.					

#### Strategic risks to manage during the journey to achieving mass customization

**Navigating complexities of co-creating with an "empowered consumer":** to achieve mass customization, companies will need to co-create care solutions with patients, taking individual needs and experiences into account. This requires companies to embrace industry convergence in the health ecosystem. A programmatic risk-enabled initiative management approach with KPIs, KRIs and key program milestones is critical to measure progress early and often.

**Having data overload resulting in disengaged patients:** with increasing use of more personalized technologies, there is a risk of overwhelming patients with unhelpful data and/or unsolicited messages and reminders, damaging company reputation, brand value and product outcomes.

**Complying with emerging and evolving data security, quality and interoperability standards around patient-generated health data (PGHD):** adhering to these standards would be critical to allow seamless data sharing among health care stakeholders and make meaningful use of huge volumes of PGHD.

**Instilling flexibility and agility in the supply chain to deal with mass customization:** increases in customization will call for greater supply chain segmentation, challenging companies to produce low volumes efficiently. More modular and agile supply chains – either physical or virtual – are needed to deal with "unique" products and unpredictable demands.

## 4 | New digital ecosystem

EY projects that by 2025, biopharma businesses will have gone digital ... new disruptive technologies would lead toward new digital business models and further value creation potential.

EY projects that by 2025, digitization will be featured fully across all stages of the pharma value chain. Digital technologies will have streamlined drug discovery, personalized and accelerated clinical trial recruitment, enhanced patient engagement and automated collection of real-world evidence (using wearables and other connected devices). Crowdsourced product and service ideas will feature widely in most pipelines. Biopharma's supply chain will have evolved into a resilient and integrated global network. Advanced analytics will have segmented and synchronized the end-to-end supply chain delivering significant improvements in product flow, packing line efficiency and inventory management.

Digitization will also have transformed customers' interactions with the health system. Symptom monitoring will be virtual, and physicians will have more opportunities to hear and address patients' concerns and needs. Biopharma firms will have a better understanding of their customers and receive real-time feedback, allowing them to adapt their product launch strategy and tactics. Digitalization will change the way value is captured through innovative pricing and payment models. Robotics and other forms of process automation will have streamlined aspects of many business support functions (such as HR and finance).

### New digital ecosystem across value chain



**Advances in technology will continue to disrupt and evolve the current business model.**

### Strategic risks to manage during the journey toward digitized biopharma

**Addressing structural inefficiencies in existing IT operations and making right technological investments:** maintaining existing systems, while upgrading and/or replacing critical infrastructure and embracing new innovative technologies to enable continuous evolution and growth is important.

**Quantifying the value and cost of digital transformation:** it becomes critical to understand how the transformation impacts the financial KPIs (clinical trial cost, sales force effectiveness, etc.) and enhance the revenue streams.

**Protecting sensitive and confidential data:** organizations need to be sufficiently prepared to manage cyber threats that have the potential to disrupt core operations and/or damage brand – by building and sustaining robust cybersecurity systems.

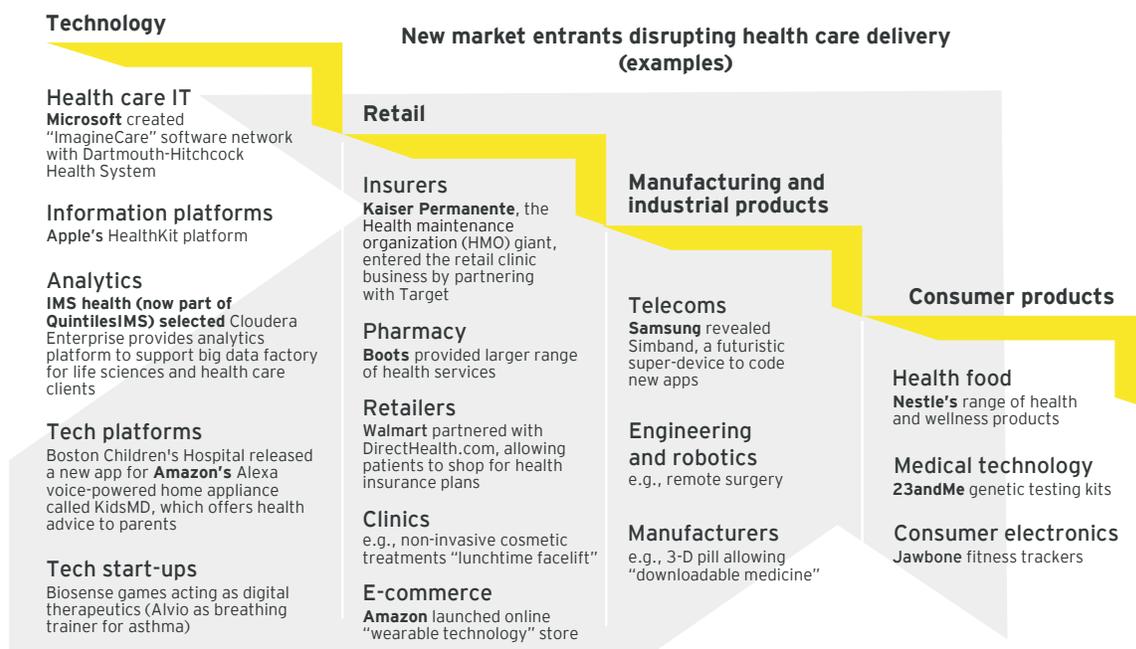
**Complying with a complex cybersecurity legal landscape:** complying with new and emerging laws and regulations around data protection and cybersecurity will require significant resources.

## 5 | New market entrants disrupting health care delivery

EY projects that by 2025, new market entrants with their consumer insight would challenge the pricing power and value creation story of traditional established players in the health care market.

New data- and technology-focused entrants will have shaken up the health care industry and be commanding a considerable piece of the health care pie. Many would have developed more affordable and convenient care options, as well as helped improve the efficiency of health care delivery and of manufacturing and supply. Health care will look like most other consumer-oriented, technology-empowered industries such as retail, automotive or banking services. Hints of this future are already here today, as consumers access online services to get their digital photos of skin conditions evaluated or to connect with a physician.

Established players will have had to rethink their role in the care continuum. Incumbents will have had to enter into smart alliances with new entrants, co-creating new models based on “providing care anywhere.” Traditional biopharma firms will lead in addressing regulatory and pricing challenges, while newcomers bring a fresh perspective on consumer engagement, and access to understanding of a large, diverse and valuable customer base. Those partnerships that maximally impact patients’ quality of life will be the most lasting and profitable.



**Meeting the expectations of “true health care consumers” will be the mantra for success.**

### Strategic risks to manage new entrants in the market

**Deciding strategically whether to compete or partner:** choosing whether to partner, buy or go it alone is critical to dealing with disruptive forces and surviving in the highly competitive environment.

**Selecting the best partner and partnership type:** shared business goals and values are critical for a successful partnership and should drive partner selection.

**Clearly defining intellectual property (IP) ownership:** there will be new challenges to the definition of IP ownership arising from uncertainty of development, structure of alliances and different approaches in different industries.

**Managing third-party risks across an increasingly complex portfolio of contractual relationships:** an increase in partnerships will call for effective third-party planning (laying down clear expectations at the start of the contract; mutually agreeing on KPIs; and then managing and monitoring risks, compliance and performance against the defined KPIs).

## 6 | Regulatory compliance: complex yet critical

EY projects that by 2025, regulatory compliance will be more complex, yet still critical to consumer trust and competitiveness.

EY projects that by 2025, the regulatory environment will still be rapidly evolving, posing both risks and opportunities for pharma companies. There will be multiple new sets of regulations around broader aspects of health care solutions – not just therapeutics but also technology standards and, significantly, data handling and security. New and evolving frameworks for the use of big data, wearables and social media data in health care will have been established by 2025. Yet regulations will also be more

harmonized across the globe as agencies and regulatory bodies overcome national differences to reap the full benefits of collaboration, resulting in faster approval processes. These will come with ever-stronger safety monitoring as well as significant payer pushback. Against this backdrop, establishing internal policies and effective systems to ensure full compliance across a widening span of regulations will be critical.

### Regulatory compliance: complex yet critical

#### Faster approval process with more globally harmonized regulations will come with stronger payer pushback.

A May 2016 proposal for harmonizing regulations between EMA and FDA could speed new drug approvals and manufacturing inspections in both regions.

Regulatory harmonization will be accompanied by continued, and probably greater, reimbursement challenges.

#### More experience with frameworks for use of big data, wearables, social media will mean defining newer boundaries.

In its 2014 draft guidance, the FDA exempted many mhealth devices from regulatory oversight.

But as more apps and other technologies are used to transmit patient data to caregivers, the FDA will take a closer look at how to regulate clinical decision support apps and other technologies that may influence care delivery.



#### FDA's role will shift from "risk regulator" to risk educator

The FDA's role will shift from "risk regulator" to risk educator in the age of personalized medicine, with patients taking more responsibility, including via improved consent mechanisms.

FDA in its 2013 report on personalized medicine stated the commitment to cooperative efforts.

#### New regulatory standards will emerge to oversee new technological and data-driven components of health care.

Disruptive trends such as direct to consumer genomic services, patient data handling and security, technological innovation that decentralize medical decisions, etc., will shape the future of the regulatory environment.

### Strategic risks to manage ever-evolving regulatory imperatives

**Continuously monitoring new regulatory requirements across the globe:** staying on top of the rapidly changing, ever-evolving and highly complex regulations across different geographies will be critical to ensure compliance and thus trust and competitiveness.

**Timely reporting incidences of noncompliance regulatory updates:** rapidly reporting incidents of noncompliance (such as falsified medicines) to relevant authorities will be critical to maintain reputation and trust.

**Appropriately training internal stakeholders to ensure company-wide compliance:** internal stakeholders need to be regularly trained in the use of standards and procedures.

**Standardizing and digitizing compliance management policies and practices to ensure real-time monitoring:** innovating old compliance management policies with changing requirements and embracing leading practices from competitors is crucial.

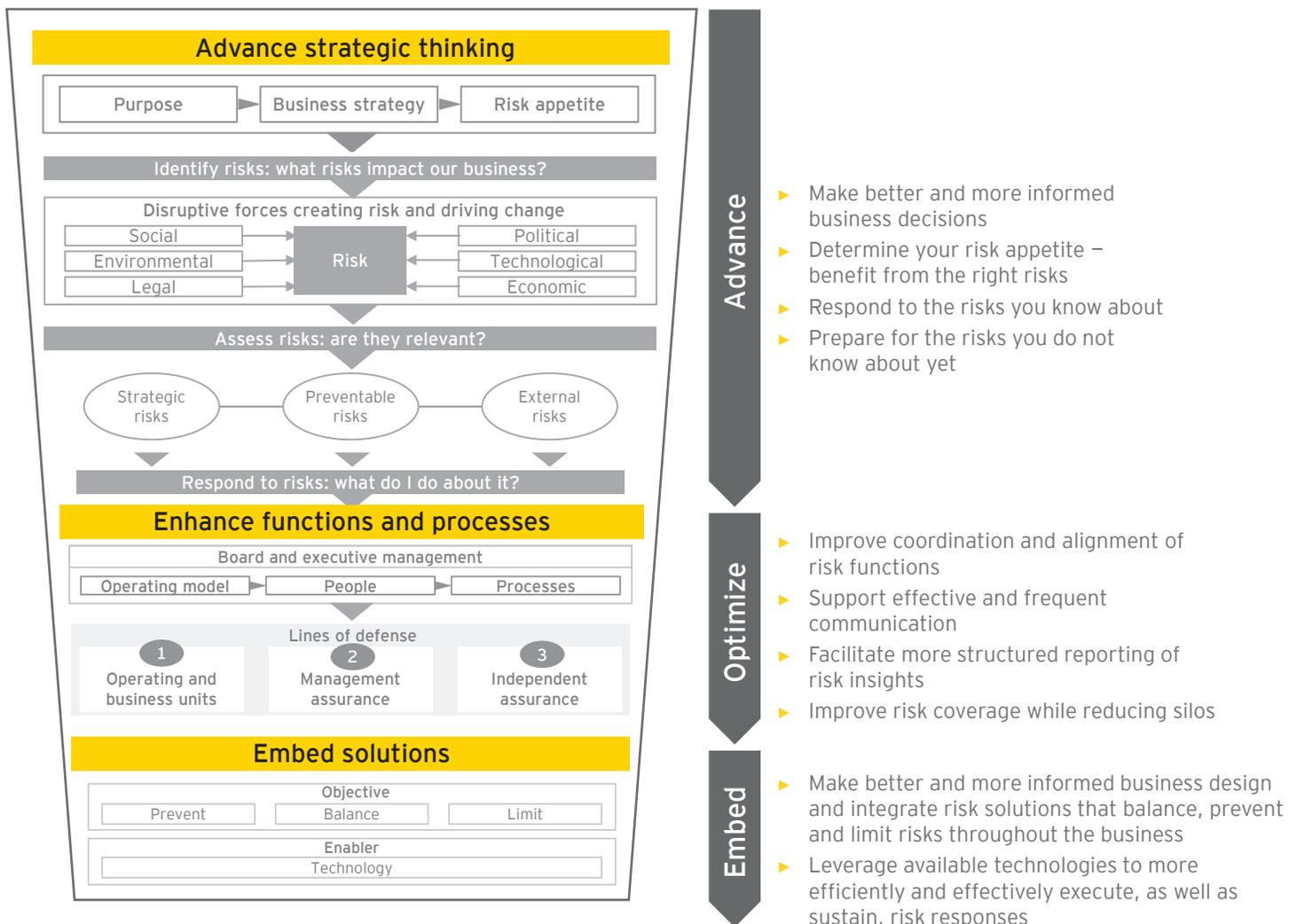
# The way forward is to ...

## ... become 'risk-aware' and embed 'sustainable solutions.'

The six trends above are already profoundly impacting the industry. It is critical for companies to assess, manage and monitor how these risks impact their value and performance by:

- ▶ Comprehensively identifying and assessing risks (strategic, preventable and external) that can help draw the most value and benefits from managing and addressing them in the short and long term
- ▶ Establishing a well-defined road map and design solutions that prevent, balance or limit risk across the organization
- ▶ Embedding risk considerations into the rhythm of the business including the strategic planning process resulting in risk-informed initiatives and programs
- ▶ Shifting management approach from being risk-averse to being risk-aware, turning risks into performance

See below how EY can help you bridge the gap in your current risk management framework:



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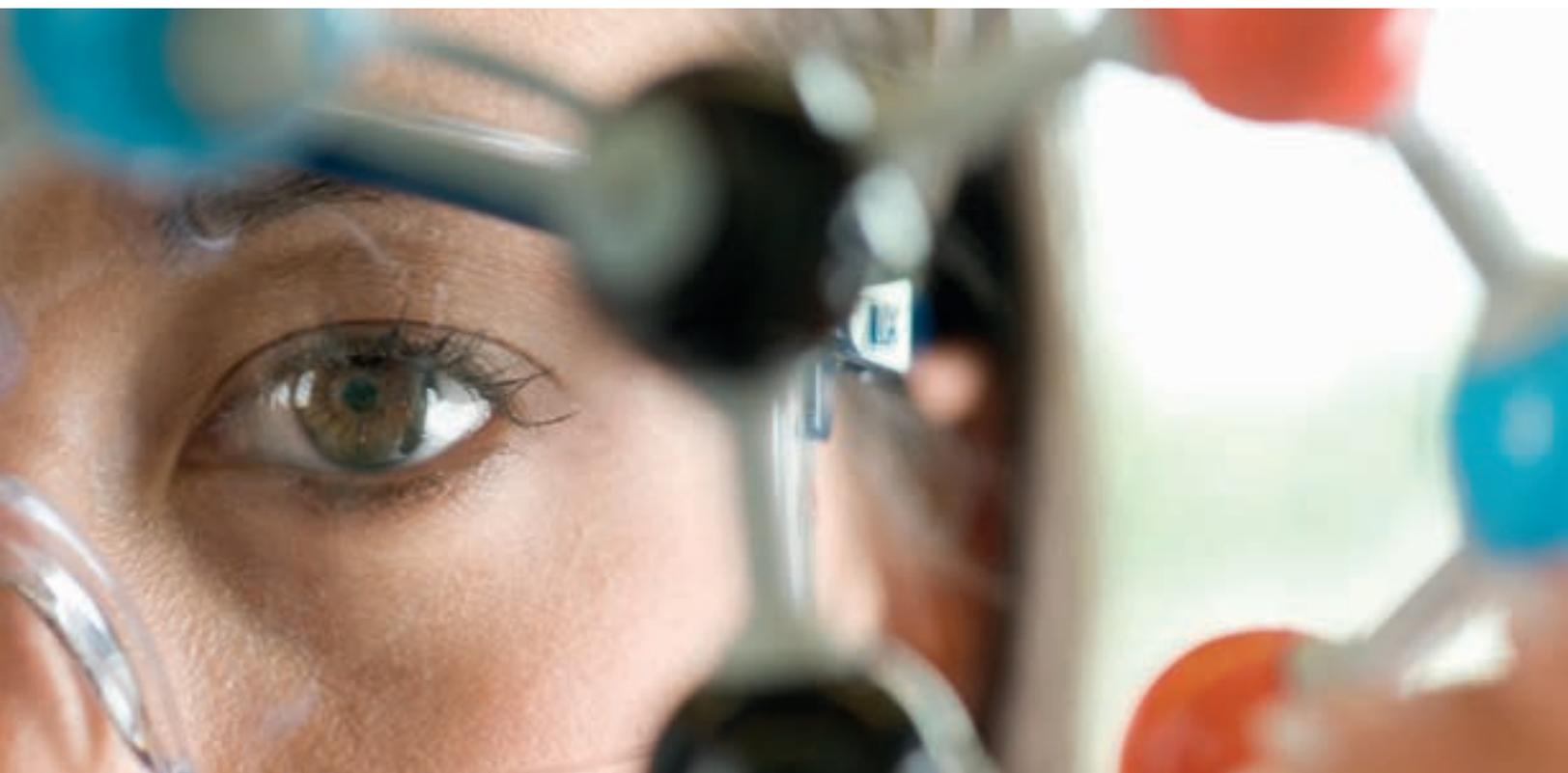
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**How EY's Global Life Sciences Sector can help your business**

As populations age and chronic diseases become commonplace, health care will take an ever larger share of GDP. Scientific progress, augmented intelligence and a more empowered patient are driving changes in the delivery of health care to a personalized experience that demands health outcomes as the core metric. This is causing a power shift among traditional stakeholder groups, with new entrants (often not driven by profit) disrupting incumbents. Innovation, productivity and access to patients remain the industry's biggest challenges. These trends challenge the capital strategy of every link in the life sciences value chain, from R&D and product supply to product launch and patient-centric operating models.

Our Global Life Sciences Sector brings together a worldwide network of 11,000 sector-focused professionals to anticipate trends, identify their implications and help our clients create competitive advantage. We can help you navigate your way forward and achieve sustainable success in the new health-outcomes-driven ecosystem.

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