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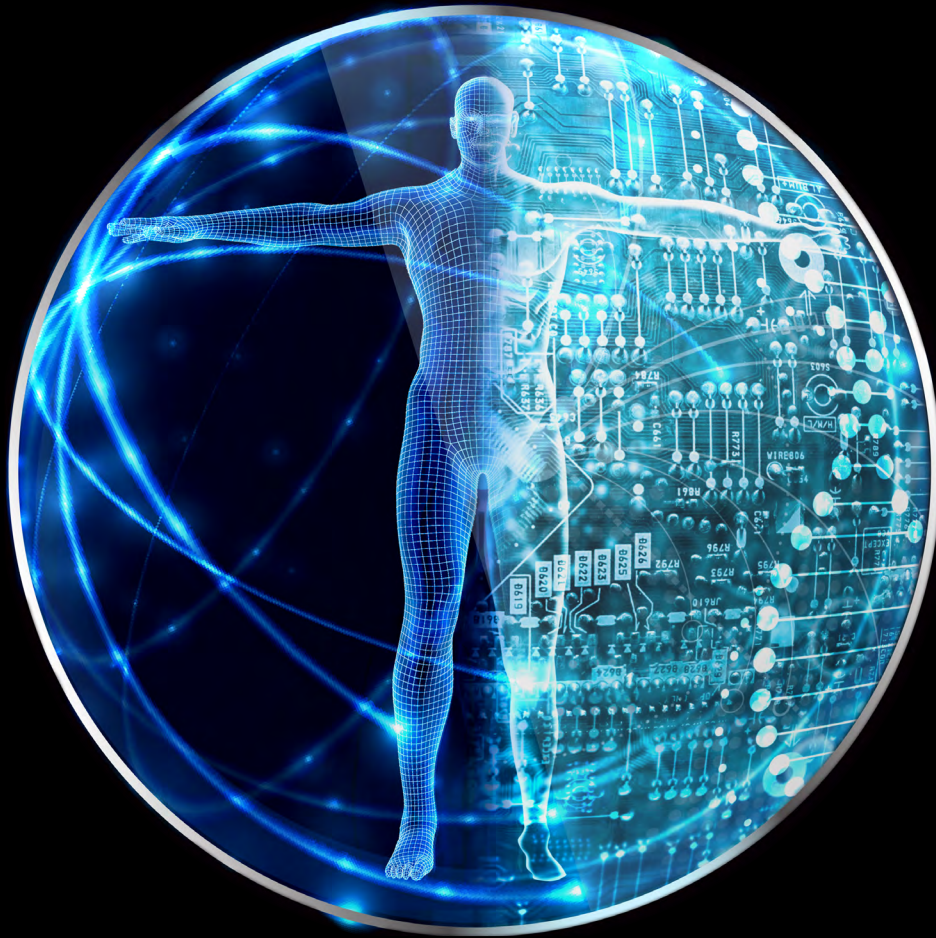
**Harnessing opportunities and
managing risk in the future of health**

Table of contents

Introduction

The life sciences and health care industry is undergoing fundamental transformations. Specific drivers such as changing demographics; burgeoning health care costs; and an evolving social, economic, and political environment are propelling tidal shifts in industry priorities and competitor dynamics. Technological and medical advances are pushing the boundaries of what's plausible today and transforming the way the future is viewed. Industry watchers agree that the future of health will likely be driven by radically interoperable data, with open platforms connecting individual, population, environmental, and institutional data sets in real time and allowing companies to leverage previously untapped or unknown data and insights. Radical interoperability could further empower consumers to focus on well-being. Seeking "sick care" could potentially be viewed as the "last resort" option.

These transformative shifts create numerous opportunities for both industry incumbents and orthogonal organizations entering into the industry to disrupt the marketplace. However, it will also be critical for business leaders embracing innovation to intelligently manage the potential risks emanating from this new future. Disruptive organizations in the future will be those that adopt one or more business archetypes, based on the value they seek to deliver in the health care ecosystem.

This report focuses on 10 emerging trends that provide opportunities as well as potential risks that are likely to have the greatest impact on the life sciences and health care industry.

Explore the top trends, specific drivers, real-life examples, opportunities, and potential negative consequences facing participants in life sciences and health care. Learn about ways industry leaders can manage the risks in order to seize opportunities.

The future of health is being shaped by a variety of drivers and resulting in fundamental paradigm shifts.

Drivers of change

Advances in and adoption of emerging technologies and medical innovation, with expanded access to massive quantities of health data, making possible enhanced offerings and an improved patient experience

Demographic changes such as an aging population, increase in chronic diseases, evolving needs of generations, and changing expectations of empowered consumers to be engaged in their health care decision making

Macroeconomic and political factors, such as protectionism hampering global trade, political instability, shifting government health care policies, and increased health care spending

Changes in industry dynamics, such as the emergence of orthogonals (nontraditional entrants) into the marketplace, drivers of rising costs, and resulting pressures on society and governments to reduce costs

Evolving regulatory environment in diverse areas including patient safety, data privacy, improved outcomes at lower costs, emergence of new incentive models, and changes driven by orthogonals and consumers

Fundamental industry shifts

Affordable health for all

Native data-oriented entrants disrupting incumbents

From care to health to well-being

Acceleration of digital health evolution

Interconnected health communities

Regulation encouraging long-term accountability

Evolution of trusted patient/caregiver relationships
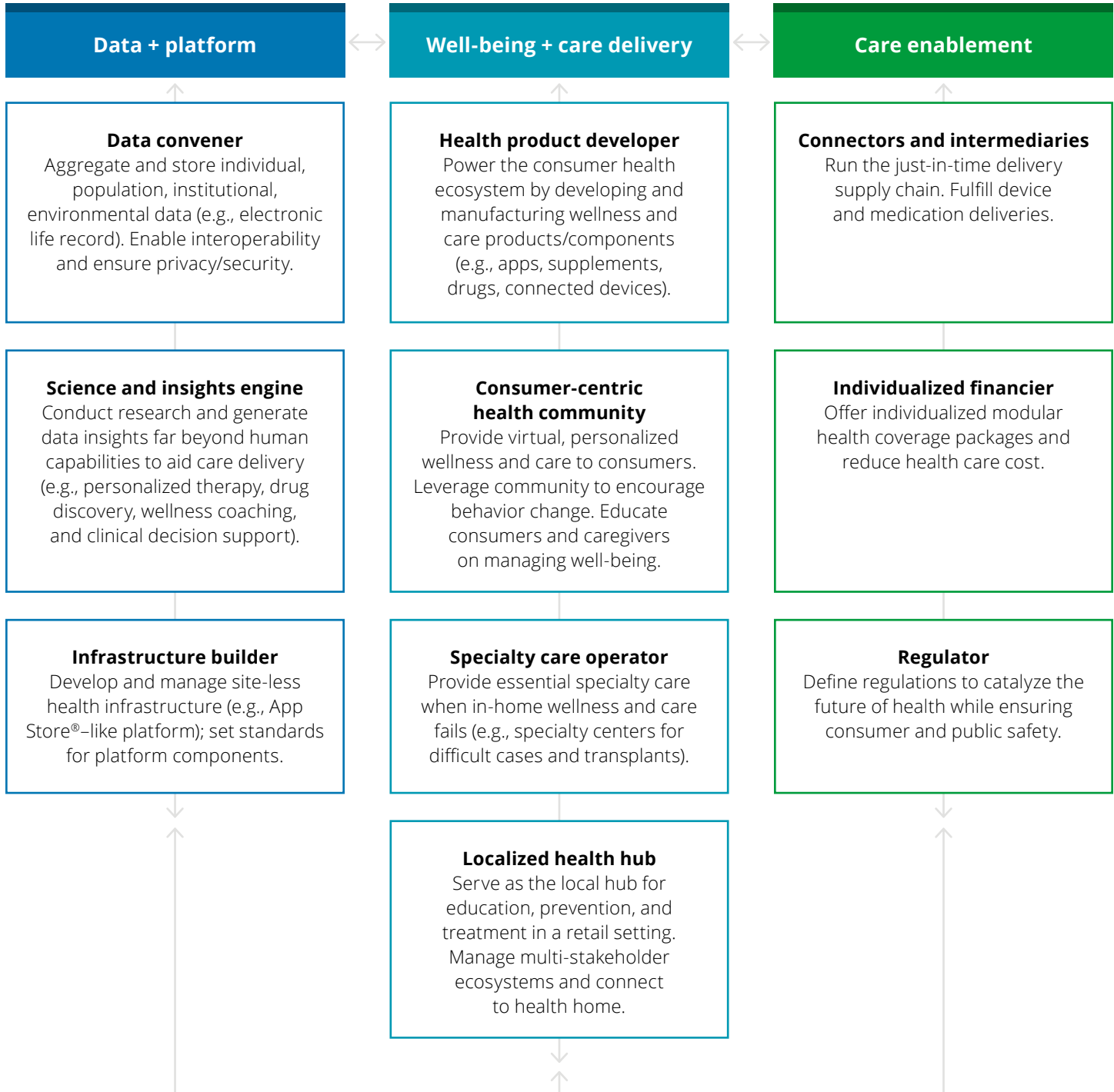
Health data ownership by consumers

"N of 1" personalized care

Personal cognitive and artificial intelligence (AI) for improved outcomes

In response to these shifts, the existing health ecosystem will change dramatically, requiring existing organizations to evolve.

These are the ten archetypes that we think will be the value drivers of the transformed health ecosystem in 2040. Tomorrow's market leaders will play in one or more of these archetypes, finding ways to differentiate themselves to create a unique business model.
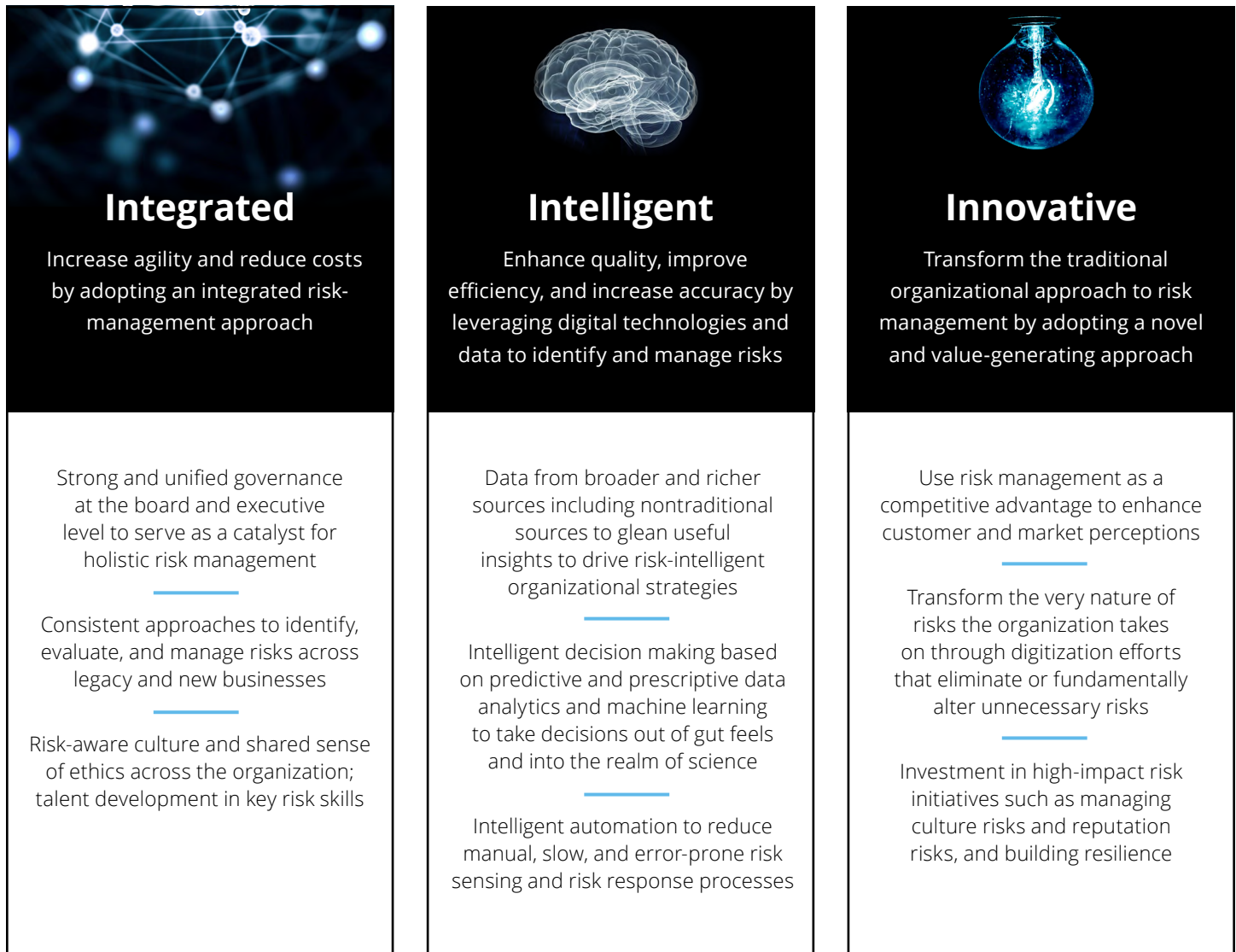
Data + platform	Well-being + care delivery	Care enablement
Data convener Aggregate and store individual, population, institutional, environmental data (e.g., electronic life record). Enable interoperability and ensure privacy/security.	**Health product developer** Power the consumer health ecosystem by developing and manufacturing wellness and care products/components (e.g., apps, supplements, drugs, connected devices).	**Connectors and intermediaries** Run the just-in-time delivery supply chain. Fulfill device and medication deliveries.
Science and insights engine Conduct research and generate data insights far beyond human capabilities to aid care delivery (e.g., personalized therapy, drug discovery, wellness coaching, and clinical decision support).	**Consumer-centric health community** Provide virtual, personalized wellness and care to consumers. Leverage community to encourage behavior change. Educate consumers and caregivers on managing well-being.	**Individualized financier** Offer individualized modular health coverage packages and reduce health care cost.
Infrastructure builder Develop and manage site-less health infrastructure (e.g., App Store®–like platform); set standards for platform components.	**Specialty care operator** Provide essential specialty care when in-home wellness and care fails (e.g., specialty centers for difficult cases and transplants).	**Regulator** Define regulations to catalyze the future of health while ensuring consumer and public safety.
	Localized health hub Serve as the local hub for education, prevention, and treatment in a retail setting. Manage multi-stakeholder ecosystems and connect to health home.	

Powered by radically interoperable data for a personalized and seamless consumer experience.

These business archetypes will need to be managed effectively to capitalize on the opportunities.

Category	Emerging risk trends	Business archetypes affected
Digital		
	Data dichotomy: Managing data risks allows organizations to harness data analytics to improve decision making	• Data convener • Science and insights engine • Infrastructure builder
	Algorithm appropriateness: Curtailing algorithmic bias and increasing transparency can accelerate new capabilities and insights	• Science and insights engine • Infrastructure builder • Consumer-centric health community • Individualized financier
	Complex cyber: Abating cyber risks can become a competitive advantage in digitally connected ecosystems	• All business archetypes
Ecosystem		
	Ambiguous accountability: Establishing accountability early enables beneficial ecosystem collaborations	• Consumer-centric health community • Localized health hub • Connectors and intermediaries • Regulator
	Redefining regulations: Proactive and collaborative approach to regulations can reduce uncertainties and foster innovation	• All business archetypes, but especially Regulator
	Synchronized supply chains: Overcoming supply chain complexities leads way to personalized consumer experiences	• Health product developer • Connectors and intermediaries • Specialty care operator • Consumer-centric health community
Organizational		
	Stringent safety and quality: Upholding safety and quality standards can expedite trust in novel solutions	• Specialty care operator • Health product developer • Consumer-centric health community • Regulator
	Financial foundations: Smart financial planning allows for experimentation with new business models	• All business archetypes, but especially Individualized financier
	Strategic struggles: Monitoring sources of strategic risk enables timely decision making to head off disruption	• All business archetypes, but especially Individualized financier
	Evolving ethics: Navigating the ethical implications of medical advancements can lead to vast health and wellness benefits	• Health product developer • Science and insights engine • Regulator

These emerging opportunities and risks can be effectively managed by applying a three-pronged approach.

Integrated

Increase agility and reduce costs by adopting an integrated risk-management approach

Strong and unified governance at the board and executive level to serve as a catalyst for holistic risk management

———

Consistent approaches to identify, evaluate, and manage risks across legacy and new businesses

———

Risk-aware culture and shared sense of ethics across the organization; talent development in key risk skills

Intelligent

Enhance quality, improve efficiency, and increase accuracy by leveraging digital technologies and data to identify and manage risks

Data from broader and richer sources including nontraditional sources to glean useful insights to drive risk-intelligent organizational strategies

———

Intelligent decision making based on predictive and prescriptive data analytics and machine learning to take decisions out of gut feels and into the realm of science

———

Intelligent automation to reduce manual, slow, and error-prone risk sensing and risk response processes

Innovative

Transform the traditional organizational approach to risk management by adopting a novel and value-generating approach

Use risk management as a competitive advantage to enhance customer and market perceptions

———

Transform the very nature of risks the organization takes on through digitization efforts that eliminate or fundamentally alter unnecessary risks

———

Investment in high-impact risk initiatives such as managing culture risks and reputation risks, and building resilience

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While applying this approach, incumbents and orthogonal players can choose their response based on their inherent strengths and strategic options.

Incumbents		Orthogonals *(new entrants)*	
Core strengths: Health care expertise, operational excellence at large scale, targeted consumer base, and existing partnerships with other incumbents	**Strategic options:** To act as innovative market leaders driving transformation or resist change and disruption	**Core strengths:** Digital and technical experience, deep pockets, access to consumers and their data, and strong analytical capabilities	**Strategic options:** To partner with industry incumbents or compete and disrupt their existing business models

Data dichotomy

Managing data risks allows organizations to harness data analytics to improve decision making

The ability of data to aid decision making is transforming the life sciences and health care companies ecosystem. From behavioral data to social determinants of health, the types of unique data being collected to drive organizational efficiencies and competitive advantage are immense. Organizations operating under the "Data conveners" and "Infrastructure builder" archetypes will strive to accelerate innovation and drive personalization of services using data-driven insights and to capitalize on their increasing value through various monetization strategies. However, the lack of standardized practices for collection, storage, and exchange is expanding the challenges of data integrity and accuracy. Further, aggregating data from new and diverse sources—medical apps, smart wearables, social media portals, etc.—raises concerns about privacy and transparency. Additionally, exchanging data in a distributed ecosystem with inadequate governance mechanisms is increasing issues of security and confidentiality. Organizations that implement strong data quality and security strategies can gain the trust of patients, regulators, and ecosystem partners and reap significant benefits.

Factors driving the trend

- Increased awareness of data's ability to meet organizational objectives such as evidence-based decision making, improved patient outcomes, and revenue opportunities

- Increased focus on analyzing and interpreting key trends and patterns from the immense amount of data available to curb rising health care costs

- Challenges in integrating data from newer and disparate sources resulting from heightened M&A deals and increased need for data sharing in the ecosystem

- Dearth of sophisticated data management and data protection skills among employees to internally handle the volume and complexity of data generated

- Increased public and regulatory scrutiny on data governance areas such as privacy, transparency, consent, and appropriate usage

Emerging opportunities for organizations

- Improved personalization of services and patient experiences from the ability to gain insights from quality data sources
- Opportunity to drive down overall costs of health care by using data insights to offer preventive and wellness-driven care
- Increased operational efficiencies and competitive advantages from the use of advanced data analytics and predictive models to guide strategic decision making
- Enhanced consumer trust and willingness to share additional data with an organization that maintains privacy and provides transparency of data use by recognizing patients as owners of their data (e.g., "Data conveners")

For example: A pharmaceutical company was able to glean valuable insights to improve business decision making with the use of an intelligent and end-to-end analytics platform. It benefited from the accelerated aggregation and analysis of disparate data, including data from third parties.

Risk factors

- Loss of reputation and public trustworthiness when organizations misuse or allow unauthorized use of data
- Financial losses due to inaccurate business decisions made using outputs of analytical models developed on unreliable or inaccurate data (e.g., "Science and insight engine" businesses suffering heavy losses from inaccurate patient data used for drug discovery)
- Noncompliance with regulations such as General Data Protection Regulation (GDPR), Medicare Access and CHIP Reauthorization Act (MACRA), Health Insurance Portability and Accountability Act (HIPAA), etc., resulting in regulatory actions such as fines, more frequent inspections, suspension of product approvals, and import bans
- Operational challenges from additional time and costs spent on cleaning and reconciling disparate data, especially for businesses that monetize data aggregated from multiple sources to provide a full picture of patient health

For example: A social media company was sued for violating patient privacy when it inappropriately leveraged patient health information data from external medical websites on its platform for direct marketing purposes. The company had not disclosed that it could track, intercept, and use patient communications with medical websites on its portal.

Ways to harness the opportunities and manage the risks

Develop and implement frameworks and standards to monitor, evaluate, and remediate data governance and protection measures

Invest in data infrastructure and controls to enable usage of longitudinal patient data sets of the future

Create robust privacy policies, data usage controls, and smart data-sharing contracts that prevent inappropriate sale or use of patients' personal and behavioral data to third-party vendors

Invest in technology to improve data privacy while exchanging data across multiple stakeholders and while preserving accuracy throughout the data life cycle

Improve data quality through investment in data standardization

Algorithm appropriateness

Curtailing algorithmic bias and increasing transparency can accelerate new capabilities and insights

Artificial intelligence (AI) and intelligent automation are radically altering health care by enabling better decision making and driving efficiencies. Business archetypes such as "Science and insights engine" and "Individualized financier" that analyze massive data sets using artificial intelligence, stand to benefit from valuable insights that can improve diagnostics, care and delivery processes, and drug discovery. However, the black-box nature of these self-learning algorithms can be difficult to understand and manage. Until seismic shifts in computing power make them significantly foolproof, algorithms are prone to human biases and faulty assumptions. Further, erroneous training data, unsuitable modeling techniques, and incorrect interpretation of algorithmic outputs increase the risks in using them effectively. As algorithms become more pervasive and complex, organizations should adopt a risk-aware mind-set to effectively manage the novel risks emerging from cognitive technologies (a field of computer science that mimics functions of the human brain). In doing so, they can reap immense benefits and provide more effective and personalized services to patients.

Factors driving the trend

- Rapid adoption of automation and intelligent systems without a complete understanding of the risk implications resulting from faulty algorithms
- Dearth of guidelines for using intelligent algorithms in patient care
- Use of biased or erroneous training data leading to incorrect outputs from algorithms
- Limitations in current levels of research, methodology, and tools to test algorithmic errors and biases

Emerging opportunities for organizations

- Higher patient satisfaction from innovative services enabled by automation and augmented intelligence (e.g., personalized and affordable health insurance plans provided by "Individualized financiers")

- Improved patient outcomes from AI-enabled analytics powering preventive care and wellness, helping identify cures for diseases with limited options currently available, and improving patient access to health services

- Streamlined and more cost-effective operations from intelligent automation and analytics

- Strengthened competitive advantage driven by use of artificial intelligence in executive decision making

For example: A technology organization was able to improve the accuracy of diagnosis for a chronic disease by using its proprietary algorithm. By using unidentified data sets and strong technical expertise, they were successful in training the algorithm to detect the symptoms faster and more efficiently than human doctors, creating a compelling case for the use of AI tools to augment human expertise in disease diagnosis.

Risk factors

- Threat to patient safety caused by erroneous diagnosis and treatment (e.g., incorrect recommendations by "Science and insights engine" businesses that use automated diagnostic applications lacking contextual data)

- Legal actions and reputational damage as a result of decisions made by algorithms, not aligned to legal, cultural, and ethical norms (e.g., racial profiling by health "chatbots" used by businesses to tap into patient data for the generation of personalized health insurance offers)

- Disruption to business operations from increased dependence on intelligent algorithms for decision making, without adequate human oversight

- Lack of trust in AI algorithms, hindering the adoption of beneficial and potentially lifesaving technology by enterprises and patients

For example: Flaws were discovered in an algorithm designed to automate the determination of medical benefits for patients suffering from a chronic disease. The designers were subjected to heavy criticism because they were unable to explain the rationale behind the adjustments made by the algorithm, raising questions on its transparency and fairness.

Ways to harness the opportunities and manage the risks

Develop an AI strategy to capitalize on the power of cognitive technologies across the organization

Assess the organization's algorithmic risk exposure and build an algorithmic risk-management strategy and governance structure, with clearly defined policies, roles, training, and complaint and incident response processes

Create standardized processes and approaches for the development, deployment, and use of algorithms across the life cycle including integrity and security of data being processed by algorithmic systems

Conduct risk assessments of use cases for intelligent automation and consider independent third-party validation that checks and balances are in place for high-risk cases

Periodically audit algorithms to test their functionality and detect undesired outcomes such as signs of bias and anomalous behavior

Complex cyber

Abating cyber risks can become a competitive advantage in digitally connected ecosystems

The rapid adoption of medical and technological advances through new, cross-sector partnerships is a double-edged sword for the life sciences and health care industry. It could help disrupt the marketplace for organizations choosing to embrace technology-focused business archetypes such as "Science and insights engine" or "Infrastructure builder." However, the shift to new technology infrastructure in a complex, extended enterprise could expose new security gaps for malicious agents to exploit. To complicate matters, attackers are now beginning to leverage AI and automation-based tools for stealthier, quicker, and more adaptable cyberattacks. Organizations that are able to build an integrated cybersecurity approach will likely be better able to effectively harness valuable health care data and be able to digitally enhance the patient experience.

Factors driving the trend

- Increased value of health care data that can easily be monetized over the dark web
- Growing complexities of addressing security needs for novel technology systems used in health care
- Rising sophistication of cyberattacks through the use of AI and other cognitive technologies
- Increased security vulnerabilities from sensitive information such as patient health information (PHI), intellectual property (IP), transactions data, etc.; exchanging multiple hands in an increasingly connected business environment
- Insufficient cyber readiness from limited investments or the lack of resources and expertise to build a holistic cybersecurity strategy

Emerging opportunities for organizations

- Increased competitive advantage through higher credibility and being the trusted brand of choice for patients
- Faster regulatory approval for digital technology solutions that require periodic updates
- Increased cost savings and operational productivity from decreased downtime powered by cyber-resilient IT systems
- Higher confidence in storing and using sensitive data in strategic decision to differentiate one's products and services

For example: A large technology provider gained significant competitive advantage by making secure data transmission possible through adoption of new security and interoperability standards and open application program interface (API). The provider does not store critical patient data on its servers and thus evokes high degrees of trust from its consumers because of its commitment to maintaining security and privacy of data.

Risk factors

- Patient health risks associated with manipulating data or tampering with medical devices and subsequent disruption in the ability to serve patients (e.g., hacking digital platforms and tools used by "Science and insights engine" businesses)
- Substantial extortion costs and other monetary losses from hackers gaining access to sensitive IP and health data (e.g., confidential patient data gets hacked from mhealth platforms and health apps due to unsecured home networks; "Data conveners" businesses becoming prime target due to high value of data involved)
- Operational issues from cyberattacks across the extended ecosystem due to increased dependencies
- Significant reputational damage, including devaluation of trade name in cases of leakage of patient health data due to inadequate cybersecurity policies (e.g., neglecting cybersecurity protocols on social media by an employee leads to leakage of sensitive data)
- Substantial regulatory fines and lawsuits from a breach of sensitive patient information in a cyberattack that occurred in the absence of adequate security protocols

For example: A regulatory body required the recall of thousands of implanted medical devices due to a cybersecurity risk. The security issues enabled the devices to be potentially accessed by third parties, allowing changes to be made to the way the devices operated.

Ways to harness the opportunities and manage the risks

Adopt a robust, end-to-end cybersecurity program that gets smarter over time through increased collaboration with ecosystem partners for increased confidence in business continuity

Incorporate security elements across the entire product or service life cycle, from design to implementation, before adding new devices and technologies to existing infrastructure

Drive security awareness and clearly define roles and accountability for security in the business and security organization, including the extended enterprise, where driving cybersecurity is especially critical

Understand dependencies and prepare for the impact of connected software and systems in order to reduce attack surfaces and to build a more resilient network

Invest in smarter access management systems such as behavioral tools to monitor and model actions of employees and business partners and escalate risky behaviors (e.g., "Data convener" businesses can leverage technologies such as blockchain to maintain secure access of data by consumers)

Establish real-time monitoring mechanisms and participate in cybersecurity consortium to track issues and vulnerabilities in technology infrastructure

Ambiguous accountability

Establishing accountability early enables beneficial ecosystem collaborations

The increased focus on developing patient-centric solutions and delivering seamless customer experiences is driving organizations to collaborate with multiple players to develop unique products and services. Such cross-sectoral partnerships, especially with new entrants such as technology and retail giants or emerging startups, by organizations such as "Consumer-centric health community" and "Localized health hub" businesses, are creating a convoluted mesh of players across the value chain. Furthermore, the outsourcing of critical functions such as R&D, pharmacovigilance, patient support, and health care IT beyond third parties to fourth and even fifth parties is expanding the external ecosystem and reducing visibility into them. These factors combined with the adoption of emerging technologies, which bring their own digital ecosystems, complicate matters of accountability and responsibility among the various stakeholders involved. Organizations that continually work with partners to establish a transparent and integrated approach to defining terms of shared accountability can benefit from the mutual trust and increased reliance on partnerships.

Factors driving the trend

- Dearth of regulatory guidelines around accountability associated with use of emerging technologies and novel business models for development of treatments and care delivery requiring regulators to act as catalysts for the future of health

- Increased risk exposure due to lack of clear accountability protocols between departments within organizations and for business arrangements with ecosystem players

- Limited visibility into the end-to-end health care value chain required to determine accountability due to rise in outsourcing of core processes

- Incomplete knowledge and awareness of operational and regulatory responsibilities among outsourcing partners and their subcontractors

Emerging opportunities for organizations

- Ability to leverage complex ecosystem arrangements in order to provide innovative services efficiently and seamlessly to patients

- Better business resilience and faster recovery from disruptions due to clear definition of roles and high transparency during and after incidents

- Clearly defined accountability allows for creative risk-sharing arrangements in order to develop new business models that are profitable for all parties involved

- Streamlined operations driven by elimination of redundant roles and activities due to clearly demarcated responsibilities for individual processes

For example: Many organizations are exploring opportunities to develop "smart contracts" using blockchain technology to improve transparency and accuracy in business processes driven by multiple third parties. Using this technology, organizations could be able to predefine and subsequently verify the performance of extended ecosystem players on a continuous and real-time basis.

Risk factors

- Lawsuits between partners or vendors to establish accountability during crisis situations such as patient harm, data breaches, privacy violations, etc.

- Loss of public trust and reputational risks from being associated with a negative incident, even if the responsibility lies with others parties involved (e.g., damage to brand caused by data breach of ecosystem partner)

- Operational challenges and cost of recovery when disruptions are caused by a lack of stakeholder accountability

- Noncompliance issues from limited awareness of an organization's compliance requirements while entering into ambiguous agreements with ecosystem players, especially with cross-industry players who may have a limited understanding of the industry's regulatory requirements

For example: A leading US health care company was fined millions for exposing the identities of patients suffering from a disease. Even though the process of communicating treatment details and medications was handled by a third party, the company had to assume responsibility for the patient privacy infringement and suffered public backlash.

Ways to harness the opportunities and manage the risks

Clearly define roles and responsibilities in business agreements in business model, operating model, and digital technology transformation efforts that entail collaboration with ecosystem partners

Embed accountability and liability clauses in partnership agreements and vendor contracts to legally protect the organization from unwanted repercussions from the extended enterprise players

Conduct periodic audits against the contractual obligations, including the involvement of fourth parties, fifth parties, and so on

Develop a strong crisis response plan that outlines responsible owners for critical functions and details a comprehensive communication plan for the organization and its ecosystem partners

Proactively simulate "unannounced" crisis situations with external stakeholders to test levels of preparedness and identify accountability gaps

Redefining regulations

Proactive and collaborative approach to regulations can reduce uncertainties and foster innovation

The life sciences and health care industry is in the midst of significant regulatory changes. Following the industry's lead on innovation, regulators are responding with modern regulatory approaches such as streamlining approvals, amending regulations, or introducing new ones. While regulators are beginning to address areas such as the use of emerging technologies, advanced scientific research, newer business models, and privacy protection, industry innovation and consumer demand are pressing for faster transformation. Some organizations adopt a reactive approach to regulatory compliance, waiting for new regulations to arrive before determining its impact and then developing compliance strategies. This approach can have a profound effect on revenues, costs, and even the ability to operate. Organizations could gain significant value with a multipronged approach to regulation, including collaborating with regulators and, where appropriate, forging ahead in areas with regulatory uncertainty. Organizations such as "Health product developers" and "Specialty care operators" could look to shape regulations through consumer advocacy by leveraging their vocal consumer base to influence regulators for balanced regulation.

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Factors driving the trend

- Advent of consumers and orthogonal organizations driving rapid and novel forms of regulatory evolution

- Increased complexity of compliance driven by intense regulatory scrutiny, increased enforcement actions, fines and penalties, and heightened standards and expectations from regulators

- Ambiguity of regulations for emerging technologies such as AI, 3D bioprinting, genetic engineering, and new products and services such as telehealth

- Higher impact of global regulations such as GDPR, medical devices regulations, and identification of medicinal products (IDMP) data standards that are adopted in Europe, given increased globalization of trade and operations

- Fragmented and siloed approach to compliance within individual operational or business functions, while overlooking the increasing complexities of regulations and enterprise-wide interconnectedness of risks

Emerging opportunities for organizations

- Reductions to overall cost of compliance from more efficient and effective models
- Opportunities to earn regulators' trust, reducing excessive scrutiny
- Competitive advantage by leveraging compliance as a catalyst for better governance and to glean useful insights to aid business decisions
- Increased flexibility and readiness to respond to changing regulatory requirements
- Opportunity to lead regulatory transformation by proactively applying self-regulatory approaches while educating regulators in newer areas
- Ability to shape innovation-friendly regulations through collaboration between industry and regulators and strong consumer backing for novel services

For example: A technology company earned acclaim as a disruptive innovator by venturing into uncharted regulatory territories in order to create novel solutions to address latent needs for its customers. It gained a large global user base and profitability by being the first in its space. Innovators may need to operate ahead of existing regulatory frameworks to demonstrate customer demand, then collaborate with regulators on developing smart regulations.

Risk factors

- Lawsuits and regulatory actions including more stringent inspections conducted at a greater frequency, issuance of warning letters, and fines from noncompliance with regulations (e.g., fine of $20 million or up to 4 percent of global revenues [whichever is higher] under GDPR)
- Reputational decline, public mistrust, and loss of competitive edge from public and media glare on noncompliance incidents
- Challenges in swiftly adapting business and operating processes to regulatory changes leading to disruptions and inappropriate business decisions made with limited clarity about the evolving regulatory landscape
- Loss of market opportunities and revenue due to reduced risk appetites to innovate in areas that do not have clear regulatory guidelines (e.g., confusion from limited guidance concerning AI-based solutions offered by "Health product developers")

For example: A health software company conducted research on innovative methods to leverage AI for identifying diseases. It received worldwide recognition for accuracy and convenience of its diagnosis technique. However, the absence of a regulatory strategy to address marketing of AI-based products for medical applications has resulted in significant delays in gaining regulatory approvals.

Ways to harness the opportunities and manage the risks

Implement an enterprise-wide strategy to address compliance risk that is developed recognizing the need for compliance in a digital era and uses the expertise of cross-functional talent

Modernize regulatory and compliance processes through digitization and automation for increased efficiencies

Invest in big data analytics and establish robust models for compliance that can adapt to changing requirements

Conduct scenario planning that anticipates future regulations and incorporates the output into business strategy

Adopt a forward-thinking mind-set to identify innovative treatment and services that customers demand, and use consumer advocacy to expedite regulations

Continuously monitor amendments to existing regulations, possible new regulations, and focus on developing self-regulatory guidelines for areas that do not have clearly defined regulatory guidelines, in collaboration with industry bodies and other ecosystem players

Work with regulators to draft guidelines and leading practices concerning research on and use of novel medical and technological advancements

Synchronized supply chains

Overcoming supply chain complexities leads way to personalized consumer experiences

Expanding choices for patients in the life sciences and health care industry and advancements in research about how individuals respond to different therapies are enabling a transformation from a one-size-fits-all approach to a personalized and targeted approach in care delivery. Organizations that require just-in-time delivery to provide faster, more convenient, customized, and closer to/at-home solutions are leveraging this customer-centric approach, which mirrors the approach pioneered in the retail industry. However, this shift in strategy is creating numerous operational challenges. Organizations would require new systems, processes, structures, and partnerships to implement and deliver individualized products and services. This innovation leads to logistical challenges such as visibility and control into the entire supply chain. Organizations that build a risk-aware approach to implementing novel technology solutions for personalization and decentralization of their supply chains could potentially increase efficiencies and cost-effectiveness and provide patients a truly personalized experience.

Factors driving the trend

HEALTHCARE
HOSPITAL
PATIENT
MEDICINE

- Focus on improving patient outcomes, leading to a greater need for targeted and personalized treatments such as precision medicines
- Increased need to differentiate products and services and gain competitive advantage by providing customized customer service such as at-home, virtual care
- Medical research suggesting that different people respond to different therapies based on genetic and lifestyle differences leading to the need for personalized supply chain, especially for "Specialty care operators"
- Entry of technology and retail giants possessing strong distribution networks and the potential to disrupt traditional supply chain models of incumbents
- Pressures to control costs vis-à-vis increased complexity from smaller batch sizes and complicated testing for individualized medicines

Emerging opportunities for organizations

- More effective treatments and better medical outcomes from differentiated products and services powered by a personalized supply chain

- Substantial increase in revenues over time from transition to effective personalized treatments from traditional one-size-fits-all approach

- Leaner and more flexible supply chain models that can adapt to more complex production and delivery processes of novel medical solutions and allow for increased visibility into operations, especially for "Health product developers"

- Increased flexibility in supply chains resulting in inventory reductions, improved efficiency in switching production to other products, and heightened negotiating power

For example: An organization earned the first FDA approval to provide direct-to-consumer genetic testing with its attempt to promote a more consumer-driven, preventive approach to health care. As consumers become increasingly more empowered and expect frictionless experiences, organizations will need to leverage novel ways of reaching them via agile supply chains.

Risk factors

- Patient harm from supply chain errors leading to inappropriate/unsafe personalized medicines reaching patients (e.g., lack of supply chain controls used by "Connectors and intermediaries" leading to spoilage of personalized medicines)

- Reputational damage and legal implications due to lack of visibility and control over third-party-driven complex supply chains (e.g., expired or defective personalized drugs reaching customers due to ineffective tracking mechanisms)

- Operational inefficiencies in handling just-in-time production operations, leading to delays and missed sales opportunities

- Financial loss due to increased exposure of IP to external players responsible for sourcing, manufacturing, and delivering products and services in a fragmented environment

- Technological challenges of managing functions with which life sciences and health care may not be familiar, such as customer relationship management (CRM)

For example: A drug manufacturer encountered challenges tracking its personalized drugs from production to delivery, customizing packaging, monitoring temperature, and providing alerts for potential delays. In addition, the limited number of treatment sites, originally intended to reduce the complexity of the supply chain, affected the availability of the drug for patients who needed it.

Ways to harness the opportunities and manage the risks

Adopt leading-edge practices and hire supply chain specialists from other highly personalized industries such as automotive and computer hardware to make supply chains customer-centric, agile, and automated

Invest in intelligent and automated supply chain systems, including autonomous supply chains leveraging technologies like robots and drones, and sophisticated patient medical record systems with CRM capabilities in order to drive operational efficiencies

Collaborate with ecosystem players to solve the logistical challenges including last-mile delivery of personalized solutions, tracking patient outcomes, and reimbursements

Invest in adequate training of care providers, such as physicians and nurses, who are responsible for recommending, educating, and helping patients adopt these novel forms of therapy

Establish risk-sharing agreements with partners to protect against supply chain disruptions

Develop employee expertise in new supply chain management techniques and processes required for the organization's drive toward personalization of services and solutions

Stringent safety and quality

Upholding safety and quality standards can expedite trust in novel solutions

Safety and quality have always been of paramount importance in the life sciences and health care industry. Industry developments such as the use of emerging technologies, innovative drug discovery and development, novel care-delivery solutions, and supply chain transformations highlight a need to review safety and quality, especially for organizations experimenting with cutting-edge care delivery and operating in archetypes such as "Health product developer" and "Consumer-centric health community." The push for speed to market and profitability in a competitive environment potentially comes at the cost of time and resources in maintaining safety and quality standards. With the increasing consumerism in the industry, quality will become increasingly more transparent, and hence critical, through various rating and review platforms. Therefore, in the future, maintaining safety standards may become table stakes for organizations—but continually upgrading quality measures, which could enable them to be vigilant and proactive in mitigating risks before they arise, will be critical. Organizations that adopt these measures faster will likely see a positive impact on their brand and reputation.

Factors driving the trend

- Increased experimentation with emerging technologies for drug development, disease diagnosis, and care delivery in the absence of regulatory guidance in some areas
- Push to accelerate research and developmental life cycles to reach the market faster, potentially at the expense of safety and quality
- Inadequate training and awareness among employees, including physicians and clinical technicians who use unfamiliar technologies for critical functions
- Lack of experience and expertise on the part of quality and compliance personnel to analyze and advise on new products or services based on novel technologies and techniques

Emerging opportunities for organizations

- Increase in overall efficiencies due to cost reductions from recalls, replacements, and waste
- Increased trustworthiness among customers from a portfolio of health solutions that are reliable and effective
- Reduced cost of compliance due to proactive measures taken to maintain safety and quality
- Higher ability to focus on continuous quality improvement techniques

For example: An organization received a patent for its novel AI-based platform that collects and integrates patient feedback from various sources. The intent of this is to tap into customer demands for improved quality of current offerings and to identify opportunities to develop new ones.

Risk factors

- Patient harm caused by safety and quality lapses associated with new products or services (e.g., patient safety risk from wrong diagnosis in a virtual consultation conducted by a "Consumer-centric health community" business)
- Financial losses and regulatory costs following a safety and quality violation requiring recalls from the market
- Supply chain delays and operational challenges after recalls of unsafe drugs and medical devices
- Bad publicity and loss of marketplace credibility for not adhering to safety and quality standards (e.g., fatal side effects when organizations that develop and manufacture personalized therapies experiment with CAR-T cell therapy, in the absence of established quality control mechanisms)

For example: A regulatory body has ordered firmware updates to a medical device implanted in patients after vulnerabilities were discovered in its security controls, making it potentially accessible to hackers. Multiple security alerts and mandatory patch updates caused unnecessary stress and inconvenience for patients.

Ways to harness the opportunities and manage the risks

Develop an enterprise-wide safety and quality management strategy, adopting an integrated approach to risk management

Design and apply rigorous checks and balances throughout the value chain to determine whether safety and quality requirements are met while experimenting with new technologies, business models, and medical treatments

Invest in social media sensing tools for real-time monitoring of customer complaints and to gain foresight into safety and quality issues

Design incentive plans for employees so that they are not tempted to put time to market ahead of patient safety

Perform periodic third-party safety and quality inspections on vendors such as contract manufacturers, foreign suppliers, etc.

Work with regulators to develop standards to demonstrate important safety implications and efficacies of novel treatments

Financial foundations

Smart financial planning allows for experimentation with new business models

The life sciences and health care industry is witnessing transformative economic changes bearing significant financial implications for organizations. The advent of outcomes-based payment is disrupting core financial models for all business archetypes, including determining the appropriate pricing and reimbursement models focused on "pay-for-performance." The increasing need for capital investments to support research, development, and innovation efforts to survive in a competitive market and rising cost pressure are challenging decisions for organizations. Furthermore, as patients assume larger amounts of direct financial responsibility for their health care, the need to provide real-time and complete price transparency becomes an additional burden for organizations such as "Individualized financiers" to consider. Organizations that are able to assess the financial performance of the business in a timely fashion; place a financial lens on strategic decisions; and invest in sophisticated financial risk modeling for strategic decisions, advanced analytics, and real-time reporting should be better able to navigate these complexities and unlock more value in this environment.

Factors driving the trend

- Pressure to rein in health care costs amid patient backlash against perceived unfair pricing and the high cost of new therapy development
- Shifting of financial risk from payers to providers, along with a move from episodic to continuous care leading to the creation of new reimbursement models such as pay-for-performance, outcomes-based contracts, new pricing models, and risk-based capitation
- Lack of experience and expertise with financial management of new pricing, operating, and business models under value-based care
- Higher pressures on liquidity and profitability due to increasingly capital-intensive markets with long lag times for returns
- Rising cost pressures from nationalism-driven protectionism driving up costs of imported raw materials

Emerging opportunities for organizations

- Potential for significant upside gains from a well-thought-through transition to new financial models (e.g., customized insurance plans by "Individualized financiers" that are based on value-based reimbursements)

- Creation of more viable business models and unlocking value from smart financial decisions taken for acquisition, divestitures, and partnership deals

- Increase in effectiveness and speed of decision making powered by real-time financial insights

- Higher financial pressures winnowing away competition and providing opportunity to gain market share through acquisitions or organic growth

For example: The health care provider industry is witnessing a large uptick in mergers and acquisitions as many organizations are looking for ways to navigate the financial pressures that come with value-based care. This transition requires significant capital investments and deep expertise that is causing providers to consider consolidations for mutual benefit.

Risk factors

- Unexpected fluctuations in costs and profitability due to a move toward outcomes-based care (e.g., unpredictable revenues hamper cash-flow forecasting for "Health product developers")

- Conflicts and litigation with ecosystem partners in cases of improper risk-sharing agreements and value-based contracts (e.g., increased liability for hospitals from the adoption of bundled payments instead of separate fee-for-service payments in cases of complex surgeries)

- Margin pressures from nonstrategic acquisitions and divestitures in order to transform business models and product/service portfolios

- Reputational damage as a result of liquidity issues and perceived financial instability

- Investment loss from funding innovation efforts that are over-hyped or not executed correctly

For example: A pharmaceutical company agreed to fully refund the insurer and patients if patients taking their drugs continued to suffer from the diseases and their conditions. Such value-based agreements could increase inclusion in formularies and insurance plans but may also have significant effects on future revenue.

Ways to harness the opportunities and manage the risks

Formulate a transition strategy toward value-based payments and invest in a reporting system that measures financial and quality performance for each patient population

Align with partners to co-develop innovative health care delivery and payment models through mutually beneficial risk-sharing agreements

Conduct a financial health-check of the product/service portfolio to prioritize investments and acquisitions that have high strategic alignment and provide greater margins

Invest in accurate and timely financial modeling and valuation solutions that leverage advanced financial analytics to investigate fluctuations in costs, revenues, and profitability

Strategic struggles

Monitoring sources of strategic risk enables timely decision making to head off disruption

The competitive landscape in the life sciences and health care industry is witnessing a paradigm shift. The entrance of orthogonal players such as technology giants, retail conglomerates, and innovative startups that have differentiated products and services, is compelling incumbents to rethink their strategic choices and move toward the winning business archetypes of the future. In addition, increasing consumer focus on the industry, where patients have more control over their health care needs and want a wide range of options to choose from, is driving organizations to develop innovative products and services. Miscalculated strategic choices when entering into M&A or partnership deals, in order to gain capabilities in multiple business archetypes, could potentially disrupt their market standing. Organizations that are able to integrate risk intelligence in their overall strategy, take calculated risks, and make data-driven strategic decisions could succeed in building an improved value proposition for patient-consumers and gain significant competitive advantage.

Factors driving the trend

- Changing customer needs and dynamics, requiring higher focus on collaborations and aggregation of diverse capabilities for a differentiated, personalized, and on-demand patient experience

- Entrance of nontraditional players with differentiated core competencies— technology companies with ability to harness data and provide personalized tech-based solutions; retail and consumer products players with strong supply chain and distribution networks that offer a wide range of health and wellness products at lower prices

- Need for agile decision making with calculated risk-taking to survive and succeed in the fast-changing marketplace

- Push to strike the desired balance between containing health care costs and investing in cutting-edge technologies, innovations, and R&D efforts

Emerging opportunities for organizations

- Significant competitive advantage and increased market share from development of innovative treatments and care delivery models, driven by strategic collaborations with nontraditional players
- High patient loyalty and enhanced brand in the marketplace for being an innovative organization that aspires to transform patient care through the adoption of digital technologies
- Cost-effective operations as a result of the implementation of leading practices and solutions from other industries
- Newer sources of revenue driven by novel business models that harness cross-industry expertise

For example: A retailer has collaborated with a health insurer to allow the insurer's customers to purchase medications and health-related items from the retailer in a bid to improve access and reduce the out-of-pocket costs. As more organizations outside of the historical life sciences and health care industry enter the market, it behooves organizations to identify synergies and venture into fruitful partnerships.

Risk factors

- Financial losses and stagnant growth due to stifled innovation and a risk-averse organizational culture that is driven by a fear of failure and hesitancy to experiment
- Operational and cultural challenges from noncompatible collaborations and M&A deals with nontraditional players
- Brand and reputational damages from not being able to strategically respond to developments driven by nontraditional players (e.g., postponing adoption of a useful technology, succumbing to the "shiny object syndrome," entering into a hasty M&A deal without proper strategic alignment)
- Lack of experience and expertise in managing operations in businesses that are very different from a company's core business (e.g., running technology platforms, managing commercial retail operations, or transforming traditional sales and marketing functions in line with the demand for personalized treatment plans)
- Loss in customer loyalty, market share, and competitive advantage from the lack of agility in adapting products and services to changing consumer needs

For example: A large employer partnered with a US hospital chain to co-design cheaper health insurance options for some of its employees. This novel agreement excluded health insurers from the negotiation and contracting process altogether. If this trend proliferates, health insurers could potentially be facing serious market disruption.

Ways to harness the opportunities and manage the risks

Establish a robust strategic risk-management system by integrating strategy and risk-management stakeholders and putting processes in place for objective evaluation of strategies for potential risks

Adopt an "outside-in" perspective, and invest in risk-intelligence programs to sense and analyze evolving marketplace factors and uncertain variables to aid business decision making

Harness the specialized differentiators of nontraditional entrants such as cutting-edge technology, lean supply chains, or innovative treatments through strategic collaborations and partnerships to strategically play in multiple business archetypes

Assess product risks while investing in new solutions, and design and validate a detailed business plan that takes into account factors such as desired functionality and features, evolving consumer needs, scope of demand, market viability, etc. in order to make well-informed decisions

Train leaders responsible for risk management in forward-looking risk-management approaches and business strategies in order to advise on strategic risk issues along with other enterprise risk issues in a dynamic business environment

Evolving ethics

Navigating the ethical implications of medical advancements can lead to vast health and wellness benefits

Medical ethics and bioethics are sophisticated and multidisciplinary fields combining philosophy and medicine with law and policy. Developments in areas such as genetic engineering, synthetic biology, nanotechnology, cybernetics, automation, and AI are further complicating the scope of these fields. For organizations such as "Health product developers" and "Science and insights engine" businesses, they create ethical dilemmas around the appropriate use of such technologies, as well as their safety and impact on society. With organizations vying to push the boundaries of innovation, it has become imperative for them to expand their purview of ethical considerations to promote responsible innovation practices. Organizations that display an ethical approach to innovation can garner respect and credibility in the marketplace.

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Factors driving the trend

- Pace of innovation superseding that of regulation, causing a dearth or absence of standardized ethical norms for experimental treatments and care delivery and technology innovations

- Growing avenues to collect, store, and use patient health and personal data, especially with the proliferation of ubiquitous health sensors, increase the potential for privacy breaches and unethical use, especially for "Data conveners"

- Increasing use of self-learning algorithms developed using potentially flawed or biased data and autonomous machines with limited understanding of social context and moral codes

- Intensified pressure to gain market share and profitability in a highly competitive environment, leading to prioritization of speed to market over caution

Emerging opportunities for organizations

- Better brand value from patient loyalty and trust gained as a result of high integrity and moral standards displayed by the organization
- Increased confidence of experimental efforts by patients and regulators due to responsible innovation practices
- Establishing an ethical culture within the organization that is aware of the organization's moral guidelines and adopts fair practices in pursuit of growth

For example: A consortium of technology players, academic institutions, and human rights groups was created to advance the ethical use of AI and to protect the interests of consumers. Such proactive measures to apply an ethical lens toward innovations and to consider unintended negative consequences go a long way to garnering public trust and credibility.

Risk factors

- Critical patient safety issues from experimentation with or adoption of medical and technological innovations, without abiding by ethical standards
- Reputational damage and public backlash to unethical organizational practices leading to a loss in customers, revenues, and market share (e.g., unfair exclusion from coverage or charging higher premiums for "at-risk" people based on predictive genetic testing)
- Regulatory repercussions in case of non-adherence to established standards around ethical medical practices, leading to regulatory fines and curtailing of ability to operate (e.g., use of gene-editing and synthetic biology techniques for nontherapeutic or enhancement purposes by "Health product developers")
- Potential lawsuits from patients and other stakeholders who are victims of unethical activities
- Slower adoption of novel medical and technological innovations, or an inability to conduct important medical research, due to perceived liabilities and fear of public mistrust

For example: According to a study in the journal Science, *researchers using two public genealogy databases could correctly uncover people's surnames around 15 percent of the time from their anonymized DNA data alone. Association of the target's identity with their genetic data could be used to pinpoint their genetic relatives—an ethical challenge with DNA testing.*

Ways to harness the opportunities and manage the risks

Include ethics as part of the strategic agenda, develop an internal charter for ethical practices to serve as a "north star" during decision making, and assign leadership accountability by creating designations such as chief ethics officer

Conduct continuous risk sensing and analysis to identify high-risk activities with potential to cause ethical issues, and develop greater oversight for them

Collaborate with industry stakeholders and academia to build ethical frameworks for the use of medical innovations

Proactively work with regulators to develop industry norms that provide ethical guidance, and at the same time, don't stifle innovation

Create an ethical culture within the organization; educate employees on the ethical use of novel medical techniques and emerging technologies and leverage behavioral analytics to track employee activities to identify unethical behaviors

Form effective information sharing, consent seeking, and data use contracts with patients and partners

Contact us

Contact us to discuss how you can better prepare for what lies ahead. We can help you identify lucrative opportunities, determine ways to manage the risks, unlock your organization's true potential, and differentiate yourself in a hypercompetitive environment.

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