

Next-gen meds

## A PIVOTAL TURNING POINT

## TACKLING CHALLENGES, CAPITALIZING ON OPPORTUNITIES

In today's dynamic and complex landscape, health industry leaders are navigating formidable challenges and exciting opportunities. The economic landscape, fraught with sustained inflation and political turmoil, adds to the complexity of the health sector. Moreover, the increasing demands of an aging demographic and the widespread occurrence of chronic diseases further complicate the situation. This reality is prompting a shift in how the health industry approaches its strategies and operational models, highlighting the critical importance of finding equilibrium between service delivery and financial sustainability.

As we begin 2024 and look ahead to the future, we believe there are seven key themes that will have an outsized influence in shaping the way that healthcare will be conceived, delivered, and financed.

## KEY THEME DRIVERS – PEST ANALYSIS

#### POLITICAL

- 2024 US presidential and congressional election & 2025 UK general election
- New & updated government program policies
- New & heightened
   regulations/legislation
   /judicial activism
- Heightened geopolitical tensions
- Sustainability focus

## ECONOMIC

- Global macroeconomic conditions
- Shifts in global trade dynamics
- Shrinking profit margins
- Cost & price pressures
- Investor and M&A trends
- Consistently rising healthcare costs

## SOCIO-CULTURAL

- Value of ESG strategies and mandates
  - Activating on social justice and health equity
  - Aging population
- Increasing chronic illness
- Emphasis on mental health
- Changing consumer/ patient expectations & demographics
- Shifts in workforce dynamics

## TECHNOLOGY

- Advancements in AI & automation
- Data availability & integration
- Data privacy regulations
- Digital & telehealth solutions
- Next-generation medications
- Next-generation networks

## BUSINESS TRANSFORMATION FOR INCREASED EFFICIENCY

#### OPERATIONAL EXCELLENCE, RENEWED VISION

In the face of ongoing health industry challenges and the broader macroeconomic conditions, organizations are compelled to transform and enhance efficiency. Health industry organizations are undergoing significant cross-functional changes to drive innovation, increase productivity, and improve patient outcomes. These efforts are being deployed while leaders are navigating significant changes in traditional business models, the introduction of novel technologies, evolving regulations, and cost pressures. Organizational leaders must assess the implications of investing or not investing in certain areas and continue to balance growth with financial realities.

## Drivers:

In today's health industry landscape, leaders are confronting challenges such as shrinking profit margins, necessitating new strategies and operating models. Recent reports reveal that 88% of industry leaders are making significant strategic changes in response to economic uncertainties, with 86% planning to use multiple strategies at once<sup>1</sup>. These challenges extend beyond the economy and include talent shortages, rising capital costs, currency fluctuations, consumer spending constraints, and Federal Trade Commission scrutiny. Organizations are also contending with challenges such as the expiration of patents, fierce rivalry in therapeutic areas, dwindling technology financing, and the repercussions of the 2022 Inflation Reduction Act, the Voluntary Pricing and Access Scheme (VPAS), and the Medical Device Regulation (MDR) legislation.

These challenges are being met at a time of true innovation and advancement in the health space. The introduction of artificial intelligence (AI), access to robust data, and next-gen medications are a few of the turning point opportunities that health industry organizations have available to them.



88%

of industry leaders are making significant strategic changes

#### Implications:

Organizations that are transforming in the name of efficiency will require strong strategic planning and mobilization capabilities to be able to truly capitalize on the potential of this trend. Leaders must be prepared to help their organizations navigate the course and rally their workforce to be able to move with a level of agility, speed, and quality. This means clearly articulating and communicating the plan to all levels, retaining top talent by committing to and investing in the company culture, and empowering the workforce through training and professional development opportunities.

## REALIZED VALUE OF CONVERGENCE

#### UNIFIED HEALTH, AMPLIFIED VALUE

The health industry has seen an evolution grounded in the integration of various stakeholders, technologies, and processes to expand capabilities and create a seamlessly connected ecosystem. The necessity for this transformation, known as convergence, is propelled by the ever-increasing demands for enhanced health delivery control, risk mitigation, superior patient outcomes, elevated customer engagement, more effective cost management, and an unrelenting pursuit of value.

As a result of these collaborative alliances, partnerships, and mergers, companies now possess greater control over various aspects of their operations and have gained access to lucrative financial opportunities. It is imperative for companies within the industry to now realize the value of their convergence efforts to remain competitive and relevant in the fluid market landscape.

> Learn more in Vynamic's **"Breaking Boundaries: The Convergence Evolution"** Insight

#### Drivers:

In the ever-evolving health landscape, organizations aim for organic growth, strategic partnerships, and diversified offerings to create value. Despite economic uncertainties, the Life Sciences sector remained strong with 376 M&A deals announced in Q3 2023, worth a total value of \$33.3 billion<sup>2</sup>. In Health Tech, ongoing capital flow underscores the sector's global importance due to health-tech convergence, with the 2023 MedTech market projected to have reached \$579.4 billion<sup>3</sup>. Moreover, rapid innovation driven by fields like AI and transformative business models such as the 'Amazon Effect' will prompt organizations to reevaluate their operations to better align with evolving customer demands and heightened expectations.

These changes address not only financial opportunities but also crucial challenges. Escalating healthcare costs are driving a shift towards holistic wellness and preventive care, utilizing innovative solutions like emerging technologies and data-driven approaches, empowering patients for long-term well-being<sup>4</sup>.

#### Implications:

Organizations aiming to leverage the benefits of convergence need to strategically focus their investments on developing strong digital infrastructures. This includes prioritizing areas such as advanced analytics, cybersecurity, and interoperability, which are crucial for delivering integrated and patient-focused care. Equally important is a cultural shift within these organizations, necessitating a workforce that embraces innovation and ongoing learning, coupled with management practices that enhance flexibility and quick response to fast-paced industry developments. To achieve this internal transformation, it's essential to establish solid, collaborative relationships across various sectors, creating an ecosystem that supports common goals and leads to better patient outcomes.

Simultaneously, staying abreast of and compliant with the evolving regulatory landscape is critical, necessitating a proactive stance in both adhering to and shaping policies that affect healthcare delivery. By embracing these strategic and operational shifts, organizations can unlock the full value of health industry convergence, positioning themselves as leaders in a patient-centered, data-driven, and collaborative care future.

## REVOLUTIONIZING HEALTHCARE THROUGH AI TECHNOLOGY

#### TECHNOLOGICAL LEAP, TRANSFORMATIVE CARE

Growing data availability and the widespread use of digital solutions have created a prime opportunity for health innovation through artificial intelligence. Al technologies have the potential to benefit all industry stakeholders, enhancing system efficiency through streamlined operations and data collection/management, faster research, enhanced risk and disease detection, more informed clinical decision making, and expedited patient treatment and access. It also could be the solution to tackle longstanding challenges like clinician burnout, patient safety, and reimbursement simplification. For industry leaders, embracing Al and technology is essential for staying ahead in a rapidly evolving industry.

#### Learn more in Vynamic's **"Why AI fails or flourishes: The underestimated role of culture"** Insight



With the introduction of any novel technology comes increased oversight and scrutiny. We have already seen this play out in the United States at the federal level with hearings on the use of and concerns with AI practices. Successful incorporation of AI into everyday business operations will necessitate dedicated staff to ensure alignment with compliance and regulations. This will be especially true for organizations that manage protected and sensitive health information.

#### **Drivers:**

In 2021, 85% of industry executives adopted AI strategies with 48% already implementing a plan<sup>5</sup>. A complementary MIT study reveals that 75% of medical staff see AI positively impacting disease treatment with 56% of health executives foreseeing AI in clinical decision making within the next decade<sup>6</sup>. The growing AI integration underscores its leading role in reshaping the health industry and enhancing patient care.

As health leaders consider these changes, it is crucial to acknowledge the substantial investment involved. Al investments in the United States are expanding remarkably, with funding surging to \$56.8 billion in 2023, expected to rise to \$68.1 billion in 2024, and projected to reach a remarkable \$81.7 billion by 2025<sup>7</sup>. In the global software industry, generative Al software is approaching a significant milestone with an estimated value of \$150 billion, as of a 2023 report. This blend of innovation and investment highlights the industry's bold progress and growing market presence<sup>8</sup>.

#### Implications:

The incorporation of AI presents substantial opportunities for enhancing patient care, expediting research, and streamlining operations. However, achieving this potential necessitates precise strategic alignment around core business operations, adept regulatory navigation, and robust data management and cyber security. This means precise strategic alignment and the ability to tactically select what types of use cases and scenarios will have the greatest impact on an organization and their customers.

The success of AI cannot be achieved in a vacuum. It must be used in partnership with a workforce that is trained and ready to use this tool to enhance, rather than replace, key critical decision making. This means leaders will need to deploy a strategy around these new processes and prioritize roadmaps to implementation, the structure of governance and stewardship frameworks, and the right training and development opportunities.

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## NEXT-GEN MEDS

#### FUTURE THERAPIES, PERSONALIZED HEALING

Recent innovations and the advent of specialty drugs mark the dawn of a transformative era in health. These breakthroughs have already yielded remarkable discoveries and approved treatments that cater to individual patient requirements, moving away from the conventional "one-sizefits-all" approach of the past. This revolutionary shift in treatment necessitates strategic adjustments in the health delivery and payer areas of our ecosystem, as these therapies require organizations to swiftly adapt to this evolving landscape.

#### **Drivers:**

In the United States, next generation medications (next-gen meds) are going through a transformative phase, showing remarkable growth. The US cell and gene therapy market, valued at \$3.22 billion in 2022, is expected to reach \$25.58 billion by 2028<sup>9</sup>, with 32 new products already FDA-approved<sup>10</sup>. In 2023, startup financing has surged, with 21 companies securing \$1.3 billion in seed or Series A funding in just one quarter, double the previous quarter<sup>11</sup>. Looking to 2025, the outlook is promising, with expectations of 10 to 20 new product approvals annually from a robust pipeline of 365 therapies in oncology and rare diseases, addressing critical medical needs<sup>12</sup>.

In European markets, challenges include cost concentration, complex manufacturing, intricate market access, and research hurdles. However, there's substantial unmet medical need, with around 385,000 patients requiring treatment for specific conditions targeted by cell and gene therapies. This patient population is three times larger than in other regions, highlighting the extensive opportunities in this market<sup>13</sup>.

#### Implications:

Next-gen meds offer the potential for groundbreaking and life changing treatments. Managing these new opportunities in a complicated reimbursement space will present opportunities and barriers for both Life Science and Health Services organizations as the market sees an increasing number of these types of therapies over the next decade. One factor to consider is the nuance and consideration it will take to launch this type of product. For Research and Development (R&D), cell and gene therapies can make diagnosis and patient selection more personalized, allowing for more efficient operations for both clinical trials and manufacturing. For Health Tech, the introduction of innovative technologies like AI and robotics will further influence manufacturing, adding to the potential for reduced cost and time while improving scalability and quality.

For Life Science organizations, these novel drugs will also require a new way of thinking about the traditional commercial model and will demand more collaboration across functions for successful product launch orchestration. For all sectors it will mean new types of business partnerships and a distinct set of skills within the workforce to lead these efforts and to better understand and plan for how these next-gen meds fit within the health system.

One significant challenge that remains unanswered for Life Sciences and Health Services, specifically providers, is who will bear the cost of these drugs and how will organizations ensure health equity? While these advancements in treatment offer astonishing hope for rare diseases and potential curative therapies, they also challenge the system due to the high investment for patients with unclear long-term benefit to manufacturers. While these drugs offer a lot of promise for the future of care, they challenge the workings of the system and thus need intentional and thoughtful strategy and planning for all health stakeholders.

## HEALTHCARE AS A SERVICE

#### CONTINUOUS CARE, TAILORED TOUCHPOINTS

The health industry is moving towards a 'healthcare as a service' model, with leaders leveraging digital platforms for scalable solutions. This highlights the need for an industry transformation to ensure adaptability and efficiency in an environment where the status quo is no longer addressing the complex challenges facing the industry. This transformation addresses cost challenges and changing demographics, emphasizing mental health and continuous patient-centered care.

Globally, health spending has reached

# \$9 trillion



The shift to 'healthcare as a service' is primarily driven by the rising cost burden on the provider sector. This increase is rooted in demographic changes like an aging population and a surge in chronic illnesses, alongside a growing number of uninsured individuals<sup>14</sup>. Globally, health spending has reached \$9 trillion, accounting for about 11% of the global GDP, driven by increased government investments in healthcare at all income levels, as highlighted in a 2022 World Health Organization (WHO) report<sup>15</sup>. The sustainability of these escalating costs is now in question, and experts believe the sector is at a tipping point.

These rising costs have triggered a digital revolution, prompting providers to adopt innovative solutions. Automation and digitization are helping to address persistent patient access barriers and workforce shortages<sup>16</sup>. Patients now demand comprehensive, cost-effective, and conveniently accessible healthcare, driving the shift to value-based care<sup>17</sup>. Flexible staffing, remote care, and time-saving technology offer solutions that introduce new ways of working to an understaffed and overtaxed workforce.

Additionally, changing patient demographics, including a greater focus on mental health, are reshaping health priorities. The WHO notes that this mental health crisis costs the global economy over \$1 trillion annually<sup>18</sup>. Consequently, addressing mental health concerns has become imperative in the modern landscape, presenting challenges and opportunities for health executives to navigate.

#### Implications:

× × × The shift to a 'healthcare as a service' model brings a stronger focus on patient outcomes, data sharing, and remote care. This new way of doing business means thinking about the traditional workforce in a new way. This workforce transformation will require dedicated time and resources to a strategic operational model and organization redesign as well as investing in workforce professional development.

Health Tech companies will also need to invest in the development of the platforms needed to help address persistent challenges in the provider sector. For providers specifically, leaders will need a strong strategy and plan to be able to mobilize through to implementation and ensure a strong customer experience.

## **POLICY IMPLICATIONS & JUDICIAL DECISIONS**

#### POLICIES SHAPE CARE, VOICES SHAPE POLICIES

Health industry news has gone from headlines to political and judicial headwinds in a way that the industry has not had to contend with in the past. Coupled with upcoming elections in the United States and across the globe, the health industry has become a political focal point. Court rulings and governmental actions will continuously shape the international health landscape, firmly establishing the enduring connection of politics and the health industry. Recognizing the consequences of policies and decisions is indispensable for strategic development and regulatory adherence for all health industry leaders and their organizations.

#### **Drivers:**

In the current US political landscape, the health sector faces legal and legislative challenges spanning from the passage of the Inflation Reduction Act, challenges to reproductive rights, transparency laws, evolving health industry antitrust enforcement, and the impact of the Executive Order on Competition<sup>19</sup>. Health equity, the shift toward non-institutional care, and the Supreme Court influence on 340B drug reimbursement also elevate the industry's political importance. At the same time there has been an increase in government scrutiny of health technology and data that the sector has had to contend with as new business practices are being adopted<sup>20</sup>.

In Congress, safeguarding Medicare and Medicaid funds, combating waste and fraud, and addressing regulations like Federally Qualified Health Centers (FQHCs), rural health initiatives, home health expenditure, and nursing facility staffing are top priorities. Financial considerations are another driving force with the Infrastructure Investment and Jobs Act (IRA) which aims to reduce healthcare costs through Medicare drug price negotiation, pharmaceutical price caps, and lower Medicare beneficiary expenses. These policy and regulatory changes are reshaping the health landscape, posing significant challenges for organizations as they adapt<sup>21</sup>.

In the United Kingdom, industry experts warn that higher VPAS rates could contribute to existing challenges in the market exacerbated by increased demand in a post-pandemic NHS<sup>22</sup>. Additionally, the EU's approval of Medical Device Regulation (MDR) compliance measures has had global implications, emphasizing the health industry's role in shaping the broader political landscape<sup>23</sup>.

#### Implications:

The health industry is seeing an increase in political focus. From navigating complex regulation and government mandates, to ensuring equal access to care, health leaders are faced with a growing challenge of staying up-to-date and informed on fast changing and hugely impactful political issues. As these legislative actions and judicial rulings begin to manifest, their effects will be felt across all sectors.

This swirling amount of activity has cascading effects on business decisions to include how regulation transfers into business operations, product launch, life cycle management of a product, and at times even company culture. This speaks to the need for strategic and tactical planning around tracking and understanding all these moving components and the ability for quick positioning when action is needed. Additionally, leaders need to know that these changes are considered newsworthy and have the potential to impact customer opinion and company reputation, especially when tied to issues of public concern such as diversity, equity, and inclusion (DEI); environmental, social, and governance (ESG) priorities; and cost regulations.

## ENVIRONMENTAL, SOCIAL & GOVERNANCE (ESG) IN THE HEALTH INDUSTRY

#### FROM OBLIGATION TO VALUE-BUILDING OPPORTUNITY

For health industry leaders, Environmental, Social, and Governance (ESG) considerations have evolved from regulatory obligations to strategic imperatives. Spanning social and political matters, organizations that want to stay ahead in the market must recognize that ESG represents a top consideration within the health landscape, evolving beyond a mere trend and anchoring as a fundamental business requirement. Adoption of a proactive ESG approach contributes to a more sustainable and ethical health industry ecosystem, enhances long-term success, and aligns with the values of a conscientious consumer base.



#### Drivers:

The significance of ESG in the market is evident in the explosive growth of ESG funds. Funds are currently projected to climb from \$18.4 trillion in 2021 to \$33.9 trillion by 2026, making it a non-negotiable part of a responsible corporate practice<sup>24</sup>. This shift in the health industry has evolved over time and now includes vital areas such as mental health and healthcare access and equity. This points to the idea that ESG priorities reflect societal changes and having a keen sense and awareness of what matters to stakeholders and customers is a dynamic process vital to an organization's success.

Additionally, as shown in a 2023 analysis, ESG deeply resonates with consumers, with 80% preferring to purchase from companies that align with their values. This highlights how ESG can strengthen customer relationships and that neglecting ESG may reduce appeal to investors and stakeholders<sup>25</sup>.

ESG initiatives are not only attractive to external stakeholders. These factors and more indicate that ESG is not a passing trend for 2024, but a powerful force catalyzing long-lasting change in the health industry<sup>26</sup>. ESG's transformative effect on organizations, particularly in talent acquisition, retention, and cultural evolution, underscores its enduring influence beyond just a transient trend in 2024. It is emerging as a significant catalyst for sustained transformation within the health industry.

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#### Implications

The competitive advantage of ESG focused companies presents an opportunity to enhance corporate reputation and contribute to a more sustainable and equitable health sector. As companies look to increase their ESG presence, leaders need to align their ESG strategies to true policy and process changes to see realized impact and change. This will mean developing business strategies and plans aligned to ESG goals and mobilizing the workforce. This includes embedding ESG efforts into the organization by identifying teams and allocating resources to select, track, and measure the growth and maturity of these strategies over time, and to clearly articulate the value that these changes are generating in the community and within the company. This requires intentional investment in culture curation to encourage the workforce to embrace any changes and to remove potential barriers to success.

For Life Sciences, Health Services, and Health Technology, the addition of health equity as a focus area within ESG represents an opportunity. It allows leaders to activate on diversity, equity, and inclusion principles that are high priority for both health organizations, their financial stakeholders, and the communities they serve.

Additionally, with these changes, increased regulation and government oversight will mean dedicated assets for compliance purposes. ESG's prevalence within the regulatory environment and its influence over changing customer demographics point to the need for long-term adoption of these policies and qualified dedicated teams to manage these new ways of working into the future.

Funds are currently projected to climb from



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## \$33.9 trillion

by 2026, making it a non-negotiable part of a responsible corporate practice

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## CHARTING A COURSE FOR A RESILIENT FUTURE

The health industry is at a critical tipping point, with multi-faceted influences that will have wide-reaching impacts through 2024 and beyond. This time of significant and thoughtful transformation demands proactive leadership and these interconnected issues, from ESG to technology, demand careful consideration. By focusing on sustainability, equity, innovation, efficiency, and adaptability, leaders can navigate these complexities to meet the dynamic market needs of today and into the future.

## CONTINUE THE CONVERSATION

Vynamic is uniquely positioned to guide health industry and Life Science leaders through these transformative times. Our expertise, commitment to excellence, and deep understanding of the industry enable us to provide tailored solutions that address the challenges highlighted above. The implications of these themes are complex, and we understand the need for robust solutions that offer more than one-size-fits-all



frameworks. Our service offerings align to the unique challenges of the present moment and give us the capabilities and expertise to offer insight coupled with tangible action and implementation for real change and a marked difference.

> We call upon leaders to partner with us in crafting a future where health is sustainable, equitable, and driven by innovation. To continue the conversation, **contact Vynamic Health Industry Advisor <u>Mindy McCrath</u> to discuss how the themes in this outlook relate to your strategic business initiatives.**

TO LEARN MORE ABOUT THIS 2024 HEALTH INDUSTRY OUTLOOK AT A SECTOR LEVEL, LISTEN TO THESE TRENDING HEALTH PODCAST EPISODES:







**Vynamic, an Inizio Advisory company,** is a leading management consulting partner to global health organizations. Our purpose is simple: We believe there is a better way. We are passionate about shaping the future of health, and for more than 20 years we've helped clients transform by connecting strategy to action. Through a structured, yet flexible delivery model, our accomplished leaders work as an extension of client teams, enabling growth, performance, and culture.



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