AI AND THE FUTURE OF HEALTHCARE

Applications, Compliance, and
Opportunities for Artificial Intelligence
in Healthcare and Pharma





Healthcare Organizations Advance Widescale Al Implementation, Though Approaches and Timelines Diverge

More accurate diagnoses. Faster clinical trials for life-saving drugs. Personalized patient communications and treatment plans. Streamlined business functions. These and myriad other applications of artificial intelligence (AI) in healthcare exploded in 2023 amid the promise of higher valuations, lower costs, reduced burnout, and better health outcomes.

But while 75% of professionals at healthcare organizations surveyed by Berkeley Research Group (BRG) believe AI-related technologies will be widespread within the next three years, only 40% have reviewed regulatory guidance in preparing to implement the technology.

These are two of the key findings from BRG's 2024 AI and the Future of Healthcare survey report, which draws on responses from 150 provider and pharmaceutical professionals—plus interviews with numerous experts—across a broad range of roles, including chief medical officers, heads of innovation, and digital transformation officers.

In addition to assessing healthcare leaders' perceptions of the AI landscape and their timelines for adoption, the report takes up several significant AI-related challenges and opportunities. For instance, the unknown impact that Washington, DC, may have in setting specific industry guidelines could be cause for concern. Between President Biden's October 2023 executive order setting AI safety and security standards and the Department of Health and Human Services' transparency rule around the use of AI in health records, the government has shown a willingness to shape how AI is used in clinical settings.

AI opportunities, timelines, and risks also vary by organization type. Pharmaceutical companies have trailed healthcare providers in this regard, as accurate results require large datasets and concerns relating to data privacy and cybersecurity remain prevalent. But healthcare providers also face notable challenges as AI plays a growing role in the healthcare delivery system—where organizations must weigh AI-related

risks against the technology's potential to streamline front- and back-office tasks through automation, as well as in diagnostics, decision-making, and care. Notably, improper usage of AI has the potential to expose patient data, raising ethical issues that providers must reconcile while keeping up with ever-evolving regulatory guidelines. However, on the provider front, generative AI has accelerated clinicians' response times to patient messages, which have skyrocketed in volume in response to the expansion of virtual care.

The survey questions covered a broad array of functional areas within the healthcare provider and pharmaceutical industries, including:

- Administration, such as finance, information technology (IT), human resources (HR), and legal
- Commercial and marketing
- Clinical trials
- Patient services
- Governance
- Supply chain and inventory management
- Drug discovery and design
- Drug manufacturing and quality control

DEFINITIONS

ARTIFICIAL INTELLIGENCE (AI) in healthcare involves the use of computers and machine processes to simulate human intelligence and perform complex automated tasks related to health and medicine.

MACHINE LEARNING (ML) in healthcare involves training algorithms on medical data to recognize patterns and make predictions without explicit programming.

PREDICTIVE AI analyzes
historical data and identifies
patterns to make predictions
about future outcomes or trends.

GENERATIVE AI can produce new content, such as images, text, or even synthetic medical data, based on patterns learned from existing data.

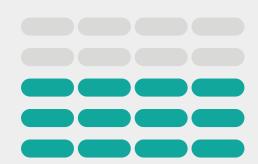
MULTIMODAL AI, going beyond text inputs and outputs, can process and analyze data from multiple sources, including biomedical data, audio from clinician appointments, ambient sensors, and more.



Three-fourths of healthcare professionals believe AI-related technologies will be widespread within the next three years.

However, differences in timelines projected by healthcare provider and pharmaceutical respondents reflect the diverse applications of Al—and the challenges of fully implementing the technology.





Over half of professionals from healthcare organizations—both providers and pharmaceutical companies—say that accuracy, data privacy, and data integrity are chief concerns in implementing AI.

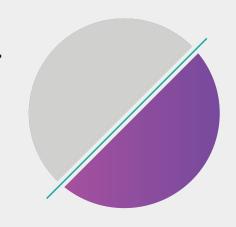
These come on the heels of new regulatory guidance from government agencies regarding Al and privacy, and the arrival of industry guidelines on Al compliance and ethical use.

Investors spent \$31.5B in healthcare AI-related technology between 2019 and 2022, and these technologies are expected to fuel more investments, and influence valuations and market value for healthcare organizations moving forward.

Recent research finds that wider adoption of AI could lead to savings of 5% to 10% in US healthcare spending-roughly \$200 billion to \$360 billion annually in 2019 dollars.

Only four in ten overall respondents indicate their organizations are reviewing or planning to review AI regulatory guidance. Despite this, a majority remain confident about regulators' abilities to develop adequate safeguards.

This report explores what can be done to prepare for forthcoming regulatory shifts and underscores the need to strike an appropriate balance in approach, so neither patient safety and privacy nor innovation are compromised.



PERFORMANCE IMPROVEMENT AND IMPLEMENTATION CHALLENGES

Healthcare Organizations Foresee Widespread Al Implementation within Three Years

Few emerging technologies in the healthcare industry have seen such significant growth in such a short period of time as artificial intelligence—and for good reason. Widescale adoption could lead to hundreds of billions of dollars in savings on US healthcare spending within the next five years, according to the National Bureau of Economic Research. The opportunity for substantial cost savings has led to sizable investment. Experts expect the healthcare industry's average estimated budget allocation for both AI and machine learning (AI/ML) will nearly double in 2024, to 10.5% from 5.7% in 2022.

It's no surprise, then, that 75% of healthcare professionals believe that AI-related technologies will be widely accepted and effectively implemented within the next three years.

That's according to Berkeley Research Group's (BRG) 2024 AI and the Future of Healthcare survey report, which draws insights from more than 150 healthcare provider and pharmaceutical professionals, as well as indepth interviews with BRG industry experts, to assess the challenges and opportunities that accompany the rapid evolution of AI in the healthcare industry.

More than four in ten provider respondents say AI already has been widely accepted and effectively implemented. This is likely a reflection of AI's myriad applications across a broad range of functions that carry limited risk of negative patient outcomes: 35% of provider respondents, for instance, say that AI is already impacting patient engagement and education, as well as administrative functions like finance, information technology (IT), human resources (HR), and legal. Using AI to streamline such tasks could help reduce administrative expenses, which account for an estimated 15% to 30% of all medical spending

"I think generative AI has a broad set of applications, and I'm quite excited about the future. I think the one thing we all have to consider is the speed with which this advancement has increased—the pace of innovation is advancement we made more progress this year than tremendous. We have made more progress this year than we made in the prior five years, and more in the prior five years than we made in prior decades. It's quite amazing to think of what may be possible."

Gina Papush – Chief Data Analytics Officer, Bristol Myers Squibb

in the United States. Roughly half of provider respondents say AI is starting to impact—or will impact in the coming year—close to a dozen efficiencies and processes.

Only 20% of pharmaceutical professionals surveyed report that AI adoption is already happening within their industry-though more than half expect its implementation will be widespread within three years. Slower adoption has less to do with the promise of AI and more to do with long timelines for drug development and greater regulatory oversight. For instance, the Food and Drug Administration (FDA) has yet to approve a drug discovered and designed using AI, and only delivered its first orphan drug designation in early 2023. This may explain why pharmaceutical respondents cite limited impact in areas such as drug discovery, safety, efficacy, and repurposing. As more drugs that are discovered and designed using AIenhanced technologies receive FDA approval, AI's impact is likely to increase.

Commercial and marketing applications are a different story. Close to one-third of pharmaceutical professionals say that processes and efficiencies are already experiencing the impact of AI—a plurality among the various applications queried. The industry's early use of AI in commercial applications could be a function of the sector's business model—much of the revenue in the pharmaceutical industry is driven by the effective marketing of products. In fact, marketing has only become more crucial for pharmaceutical companies, which in early 2023 bypassed tech to rank as the second-biggest spender on ads by industry.

While AI has yet to reach its full potential in the pharmaceutical landscape, the overall healthcare industry is poised to deliver on the promise of AI.

"The commercial side of the pharmaceutical industry is ripe for a push toward more effective AI use in marketing, pricing strategy, and contract decisions. AI can optimize datasets or streamline repetitive tasks in these areas with substantial upside and limited risk."



Clay Willis - BRG Director

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Al's Impact on Processes and Efficiencies Extends across Multiple Applications

Amongrespondents who believe AI will impact processes and efficiencies, a large majority expect a moderate or significant impact across twenty different pharmaceutical and provider applications, including patient safety, treatment personalization, clinical trials, and drug pricing.

Over half of provider respondents say AI advancements in diagnostics and imaging (55%), patient safety (54%), future health predictions (53%), and preventative screenings (52%) will significantly impact their industry. More than 40% of provider respondents believe that AI will significantly impact every application queried in our survey—from operational functions such as administration, revenue cycle management, and supply chain management to patient management functions, including patient engagement and treatment personalization.

"The excitement around AI in healthcare is real, but it's important that hospital and health system leaders avoid getting caught up in the hype and strategically target the specific needs they want to address. We're already seeing AI used to improve front-office tasks like appointment scheduling and check-in, as well as to address administrative burdens for clinicians and staff. By implementing AI thoughtfully, organizations can enhance patient experience, empower their staff, and modernize workflows."

Paul Osborne, MBA - Managing Director, BRG



What makes AI actually AI? Over the past year, the term has become a catchall for many technological applications, leading to misunderstandings about the capabilities and limitations of different AI systems. Our survey asked healthcare professionals about the distinction between two of the most prominent AI applications: generative and predictive. Generative AI—which includes large language models also known as AI chatbots—focuses on creating new data based on patterns and information it has learned during training. Predictive AI is aimed at forecasting or making predictions based on existing data patterns.

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Providers positive perception for generative Al over the next 12 months

83%

Pharmaceutical industry positive perception of predictive Al over the next 12 months

The distinction matters. A large majority of healthcare professionals expect generative and predictive AI to have a positive impact on processes and efficiencies over both the coming year and the next thirty-six months. But pharmaceutical professionals and provider respondents diverge on their perceptions of these two AI-driven technologies.

"The term 'generative Al' has entered common parlance for a much wider group of stakeholders over the past year. But it's also being misused in the same way that Al—and even 'machine learning'—is commonly misused. I often see 'generative Al' used as a surrogate for any sort of machine-driven analysis, but that's not the case—it is a subset. We need to ensure that we're educating ourselves and using these terms accurately."

Zachary Coseglia, JD – Cofounder and Managing Principal, R&G Insights Lab (an innovative compliance and culture consulting practice at Ropes & Gray) Increasingly, studies are documenting the use of AI in medical imaging and diagnostics. One high-profile study published in 2023 found AI could detect breast cancer in mammograms as effectively as experienced radiologists, enabling doctors to take on more advanced diagnostic work. Advances in multimodal AI may also enable AI-driven tools to analyze heart and lung abnormalities and identify diseases based on tissue samples in the near-future. The potential for generative AI to improve data processing and advance these successes is substantial too. Hospitals perform 3.6 billion imaging procedures annually, generating a massive amount of data—approximately 97% of which goes unused.

Pharmaceutical industry respondents believe AI will have the most significant impact on clinical trials and supply chain and inventory management, with 83% saying each will have a moderate or significant impact on their industry. Bristol Myers Squibb has already begun forming strategic partnerships to explore the many ways AI can enhance the design and execution of clinical trials, such as optimizing endpoint definitions, patient subgroups, and treatment effect estimation. Partnerships like these are fast becoming table stakes in the industry: Swiss pharmaceutical giant Roche struck a deal with Nvidia in late 2023 to improve its AI platform for drug discovery, and both Eli Lilly and Novartis have partnered with Isomorphic Labs, a corporate spinoff of Google's AI research and development division DeepMind, to advance their foray into AI-driven drug discovery.

Meanwhile, pharmaceutical companies may be looking to manage their supply chains more efficiently by leveraging <u>predictive analytics</u> to forecast demand—especially amid geopolitical tensions and lingering shortages spurred by COVID-19 outbreaks in China.



"We've explored AI from bedside to back office. What we've learned is that, to utilize AI tools while limiting risk, healthcare organizations need to have clear understanding of where the tools will be applied, the potential benefits, and the risks. Vendors and developers need to be able to clearly explain algorithms; describe implications for bias and its prevention or remediation to ensure outcomes are safe and equitable; and meet security standards. Transparency is critical."



Lisa Stump, MS – Senior Vice President and Chief Information and Digital Transformation Officer, Yale New Haven Health

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REGULATORY AND COMPLIANCE LANDSCAPE

Accuracy and Data Privacy Remain Top Concerns for Healthcare Organizations When Leveraging Al

The arrival of generative AI has garnered an enormous amount of attention from regulators, which see its reliance on digital infrastructure as a cyber vulnerability—and its open architecture as a feeding ground for violations of patient trust. In response, government agencies have addressed a range of AI-related cybersecurity and data privacy concerns in recent months, including the US Department of Health and Human Services releasing specific guidance on data privacy involving ChatGPT and the FTC opening an investigation into OpenAI.

Accuracy concerns may stem from the availability of quality data to train input models. As precise data is a commodity not often accessible for AI/ML, it can become much more challenging to produce accurate predictions—especially if datasets include many variables and are sparsely populated. In an industry where the threshold for error is slim and a misdiagnosis or mis-prescribed medication can endanger a patient, healthcare organizations are paying close attention to this issue.

"One of the concerns with AI is the collection of patient data and private information into the large language model. Whether healthcare providers and vendors are using a closed or open version of AI is important, as these AI tools may have a large impact on the potential for anonymous data to be reidentified."

James McHugh, MBA – Managing Director, BRG

These trepidations are shared among the industry itself. Well over half of professionals at healthcare organizations—provider and pharmaceutical respondents both—say that accuracy, data privacy, and data integrity are among their chief concerns in implementing AI.

As for data privacy and cybersecurity threats, AI could use outside information to reidentify an anonymized patient in different contexts—a violation of the Health Insurance Portability and Accountability Act (HIPAA) and a huge risk for providers.

<u>AI-related deepfakes</u>, which could be used to impersonate health system executives, are also chief among their concerns.

The upshot is that these concerns could be driving the adoption of established rules, protocols, and controls for AI across the sector. The majority of healthcare professionals indicate their organizations are at least taking or considering steps to ensure the proper implementation and use of AI technologies.

Nearly 60% of provider respondents, for instance, are providing some form of internal training and education on AI, and 55% of them are establishing AI-specific guidance on proper use. Pharmaceutical companies are taking a similar tack. To date, the use of AI has mostly been limited to approved functions, according to 53% of professionals in the industry, and half say that human oversight and reviews are required.

While the healthcare sector has taken steps to self-regulate as a matter of necessity, it still has more to do. Just four in ten of the total pool of respondents (37% of provider respondents and 44% of pharmaceutical professionals) indicate their organizations are either reviewing or planning to review regulatory guidance to ensure proper AI implementation. Compliance teams at healthcare organizations can benefit from collaborating with regulatory agencies to find solutions going forward.

"There has been no clear guidance or framework from regulatory agencies on the usage of AI and machine learning in drug development. For now, pharmaceutical companies are pushing the envelope and have applied AI and machine learning in a myriad of ways—whether it involves using AI in drug discovery, patient selection in clinical trials, or predicting patient prognosis and clinical and safety endpoints."



Wendy Cheng, PhD - Managing Director, BRG

Healthcare Organizations Confident in Ability to Comply with Future AI-Related Guidance

Most professionals—75% of provider respondents and 56% of pharmaceutical professionals—feel confident that future regulation and guidance will provide necessary guardrails for proper implementation and use of AI. However, the views between the two respondent groups diverge on the current state of AI regulation, with provider respondents more confident in today's AI regulatory landscape.

For instance, six in ten provider respondents view current AI regulations and guidance as providing adequate safety measures for the use of AI. This optimism may reflect trust in the burgeoning number of sector-specific guidelines—such as those unveiled by the American Medical Association in December 2023—aimed at establishing a consistent governance structure for advancements in healthcare technology. Of provider respondents, 87% are also confident in their organizations' ability to comply with regulations, while indicating that HIPAA violations, accuracy, safety data privacy, and ethical standards remain top of mind.

In contrast, only 34% of pharmaceutical respondents agree that current AI regulation and guidance is sufficient, perhaps driven by the sentiment that regulators are struggling to keep pace with rapid innovation. For example, the FDA was inundated with close to 300 applications that incorporate AI/ML in drug development from 2016 through 2022—with almost all of them filed in the last two years.

Despite these concerns, nine pharmaceutical professionals express confidence in their organizations' abilities to comply with regulations over the next thirty-six months. This optimism may suggest that pharmaceutical professionals expect regulatory agencies to deliver AI guidance soon, providing some much-hoped-for certainty around compliance. Respondents who have concerns around compliance point to data privacy, integrity and safety requirements, intellectual property (IP) protections, patent requirements, and the uncertain future of regulatory guidance.



"With thoughtful implementation and careful oversight to ensure equity, transparency, and effectiveness, AI can be transformative for healthcare delivery, improving quality and patient safety, and reducing administrative burdens."

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Christopher Longhurst, MD, MS – Chief Medical Officer and Chief Digital Officer, University of California San Diego Health

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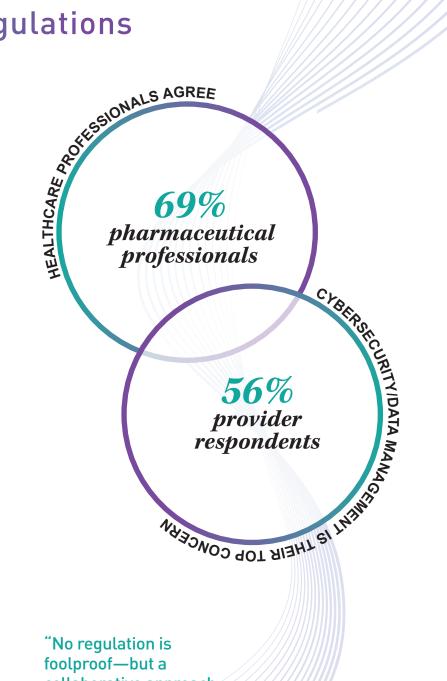
Shaping New Regulations

Professionals across all healthcare organizations—nearly 70% of pharmaceutical professionals and 56% of provider respondents—agree that cybersecurity/data management is their top concern when it comes to regulatory compliance and/or litigation exposure.

Their focus is understandable. Without a comprehensive federal law governing online privacy, executives may be worried that new legislation—such as the proposed American Data Privacy and Protection Act (ADPPA) or state laws—will contain provisions addressing algorithmic accountability and fairness that could potentially expose them to risk.

Data privacy concerns around generative AI usage in the healthcare industry largely fall under the purview of HIPAA and the FTC's Health Breach Notification Rule. In 2023, the FTC took an active stance on enforcing privacy standards in the healthcare industry, fining companies such as <u>GoodRX</u> and <u>BetterHelp</u> for unauthorized disclosures of consumers' personal health information.

As far as regulators' approach to AI-related guidance, about seven in ten healthcare organizations believe that safety and efficacy should be weighed equally alongside innovation. Pharmaceutical respondents believe that drug safety and efficacy should be regulators' leading priority as they develop AI policy and compliance standards. In contrast, almost 80% of provider respondents think regulators should highly prioritize their previously cited concern—cybersecurity, data management, and privacy—as it pertains to AI use.



"No regulation is foolproof—but a collaborative approach to policymaking can help provide better outcomes. The healthcare industry has a responsibility to contribute to better Alrelated guidelines, and the best way to do that is to partner with regulators and find the best path forward."



Gina Papush – Chief Data Analytics Officer, Bristol Myers Squibb

ALAND THE FUTURE OF HEALTHCARE

CORPORATE OPPORTUNITIES AND INVESTMENT OUTLOOK

Investments Fueled by AI Are Likely in the Coming Year

Investors poured \$31.5 billion into healthcare AI between 2019 and 2022—and while fundraising cooled in 2023 amid a global dealmaking slowdown, healthcare organizations continue to show great enthusiasm for AI and its effect on merger and acquisition transactions and other investments. In fact, close to three in five survey respondents say their organization is very likely (21%) or somewhat likely (37%) to be involved in an AI advancement-related transaction or investment over the coming year.

This positive outlook, even as economic uncertainty persists, may be a testament to the technology's staying power and value proposition. It is estimated that wider adoption of AI could lead to savings of 5% to 10% in US healthcare spending—roughly \$200 billion to \$360 billion annually in 2019 dollars.

ARTIFICIAL INTELLIGENCE IN HEALTHCARE MARKET SIZE (US BILLION)

\$29B 2024 \$53B 2026 \$100B 2028 \$187B 2030

Source: Precedence Research, Artificial Intelligence (AI) in Healthcare Market (February 2023).

AI-Related Healthcare Technologies Fuel Optimism in Valuations

The global AI in healthcare market size was estimated to be \$15.1 billion in 2022, and executives are taking notice. More than two-thirds of healthcare organizations are at least somewhat optimistic about the impact of AI-related technologies on valuations over the coming year. The reason, according to one of our survey respondents, is simple: "AI will not only better streamline healthcare but also impact patient outcomes. If this can be realized, it will definitely increase valuation."

This is especially true for provider respondents, 85% of whom hold positive expectations for AI-

related healthcare technology and its influence on valuations. The 9% of provider respondents who are pessimistic about AI's impact on valuations cite fears around the rapid pace of development and uncertainty. Diagnostics and imaging are most often cited as the greatest driver of value at healthcare organizations (chosen by 51% of provider respondents), followed by clinical decisions (33%).

In keeping with their less bullish sentiment toward AI, 66% of pharmaceutical respondents say they are optimistic about the impact of AI-related pharmaceutical tech on valuations

for the next year. One in five respondents in the pharmaceutical industry remains pessimistic, citing glitches, unknowns, and a lack of maturity. On a brighter note, the use of AI in supply chain, drug discovery, and administrative functions is expected to generate the greatest value in the pharmaceutical industry, where billions of dollars are routinely spent in the development, discovery, and approval of new drugs.

"Al is no longer an academic discussion or a dinner topic. C-suites and boards of directors across the healthcare sector have to identify which areas of Al will be the most impactful, understand implementation timelines, and have the self-discipline to fund the education process around this swiftly evolving technology."



Tom O'Neil, JD - Managing Director, BRG

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Opportunities—and Challenges—Lie Ahead

The healthcare industry greatly values the advancements and improvements afforded by AI. In this fast-paced environment, however, it is important for healthcare providers and pharmaceutical companies to simultaneously evaluate benefits and roadblocks—with an understanding of how evolving regulations may impact investment and timelines.

Here are five takeaways on how to prepare for the AI revolution in healthcare:

1. Engage proactively with regulators

As the regulatory environment takes shape, healthcare executives have the responsibility and opportunity to collaborate with lawmakers and rule makers in developing a regulatory framework that balances innovation, efficacy, and safety. In particular, the pharmaceutical industry should engage in regular communications with the FDA to ensure that industry applications and approaches are aligned with the agency's guidance and thinking (once available).

2. Advance thoughtfully

AI can bring immense value to providers and pharmaceutical companies, and executives are rightfully bullish—but when it comes to dedicating significant resources to AI, healthcare organizations should tread carefully in today's uncertain regulatory environment. Rather than pursuing the latest AI technologies just for the sake of it, healthcare executives must ensure that they're solving meaningful problems—and that newly adopted AI tools align with their organizations' core values. To that end, they should build close relationships with technical leads, internal AI experts, and vendors. For organizations that lack expertise—or are unsure how to capitalize on this breakthrough technology—it may be wiser to evaluate and/or establish a partnership with a firm adept at implementing AI initiatives and tools. Doing so could even accelerate adoption and implementation.

3. Track and adapt to new technologies

While it may seem like generative AI has just arrived, multimodal generative AI, which can holistically process different data types such as text, visual, and audio, is well underway—and could bring the technology even closer to human intelligence. While healthcare organizations shouldn't necessarily make wholesale changes just yet to accommodate innovations like these, they should monitor such advances and be open to experimenting with them. In doing so, they should take adequate precautions to ensure these technologies are accurate and being used in the way they were intended.

4. Have a robust governance model

Most provider and pharmaceutical IT and security governance models are inadequate to manage AI development and deployment. A strong interdisciplinary governance model should be established that manages AI, innovation, and automation initiatives throughout the healthcare enterprise. These are not functions where an organization simply can assume IT has sole responsibility or, worse, departments are rolling out initiatives independently.

Over the past decade, healthcare organizations have done much to capitalize on AI tools and their associated benefits: providers, for instance, have made significant technology investments to improve processes and patient care, while pharmaceutical companies have deployed AI in key areas like drug discovery. But more can be done to accelerate these efforts. Providers should continue to build on their investments by targeting AI solutions that solve specific challenges, positively impact the patient experience, and produce greater savings and efficiencies. Similarly, pharmaceutical companies should leverage their experience in AI-driven drug discovery to bolster implementation in other core business functions, such as administration and operations. To enhance their implementation of AI across applications like diagnostics, prognostics, and drug development, pharmaceutical companies should also leverage "fit for use" data in model training and testing for AI/ML development and applications; and analyze the results using rigorous, scientific standards.

Demographics

BRG surveyed 150 professionals in the healthcare and pharmaceutical space. The online survey was conducted in October 2023 with the help of a panel provider, Dynata.

Respondents represented various functions and departments in the healthcare and pharmaceutical industries. Responses were anonymous, and the data were analyzed in the aggregate. Due to rounding, numbers presented throughout this report may not add up precisely to the totals provided.

Industry

Healthcare

Provider

43% Company

Job Function

44% **VP/Director**

Executive

C-Suite or **Another Company Office**

Other than CEO

Member

President/ Owner/ Founder

Pharmaceutical Company Department

Administrative and Support (finance, IT, HR, legal)

Research and Development Including Health **Economics** and Outcomes Research

Marketing

Medical Affairs

Manufacturing **Production**

Access and **Pricing**

Assurance

Healthcare Provider Department

Administrative and Support (finance, IT, HR, legal)

Clinical Services (medical, diagnostic, surgical)

Patient Care Services (nursing, case management, social services)

Relations and Customer Service

Assurance

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