



RISK MANAGEMENT FOR GENERATIVE AI-ENABLED MEDICAL DEVICES

Harnessing Innovation – Maintaining Patient Safety



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MACHINE LEARNING SYSTEMS



INTRODUCTION

- Generative AI
- Medical Devices
- Risk Management



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New Opportunities Enabled by GenAI

- Personalized Treatment Planning
- Enhanced Medical Imaging
- Intelligent Clinical Decision Support



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RISK CONSIDERATIONS

- Data Quality and Harmful Bias
- Model Transparency and Explainability
- Real World Performance Variability





GOVERNANCE CONTROLS

- Regulatory Compliance
- Ethics Review Board





TRAINING & VALIDATION CONTROLS

- Robust Training Protocols
- Rigorous Validation Procedures





FEEDBACK MECHANISMS

- Continuous Monitoring System
- User Feedback Integration





REAL WORLD PERFORMANCE EVALUATION

- Post-Market Surveillance
- Performance Benchmarking





WHAT ARE THE TRENDS?

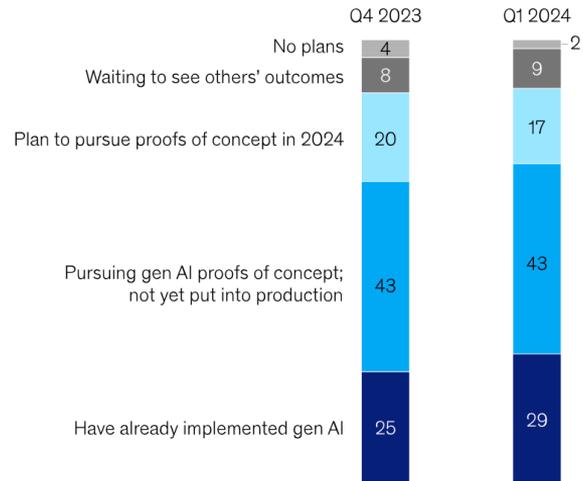
INTEGRATION & INTENTIONS

Integration and intentions

In the Q1 2024 survey, a majority of respondents say that their organizations are either already using gen AI tools or are testing them out. Most of the surveyed respondents are in the proof-of-concept stage with gen AI, as stakeholders contemplate trade-offs among returns, risks, strategic priorities, governance, maturity, and other factors. Yet despite the industry's general interest in using AI, there is still a consistent portion of respondents without any plans to pursue gen AI or who are maintaining a wait-and-see approach.

Most respondents say their healthcare organizations are at least pursuing generative AI proofs of concept, if not already implementing the technology.

Healthcare organizations' plans to use generative AI (gen AI), % of respondents (n = 100)¹



¹ Respondents include 40 payer, 40 provider, and 20 healthcare services and technology groups; ~30% are C-level executives, and ~30% are from >\$10 billion revenue organizations.

Source: McKinsey US survey on gen AI in healthcare, Dec 12–14, 2023, and Mar 11–13, 2024





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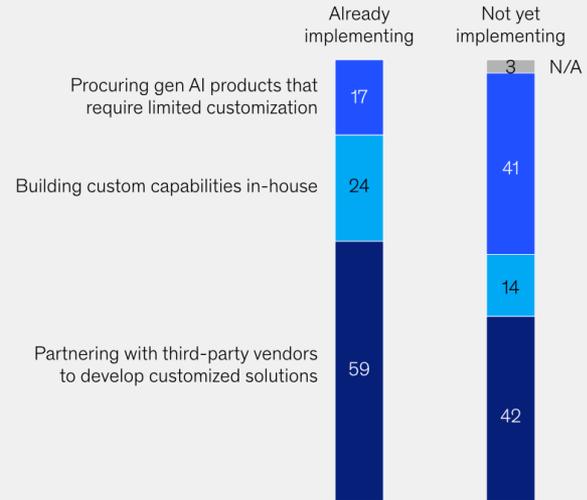
PARTNER OR PIONEER

Partner or pioneer

Among those surveyed who are implementing gen AI, 59 percent are already partnering with third-party vendors to develop customized solutions, and 24 percent report plans to build solutions in-house, while only 17 percent expect to buy off-the-shelf gen AI products. Among those who haven't yet implemented gen AI, 41 percent say they intend to buy gen AI products, which may be driven by this population's concerns with risk (57 percent are not pursuing gen AI, because of risk considerations) and technology needs (29 percent).

Surveyed organizations that are already implementing gen AI capabilities do so primarily through cobuilding partnerships.

Healthcare organizations' plans for generative AI (gen AI) adoption, by implementation level, % of respondents (n = 100)



Source: McKinsey US survey on gen AI in healthcare, Mar 11–13, 2024

McKinsey & Company





WHAT ARE THE TRENDS?

ROI for GENERATIVE AI

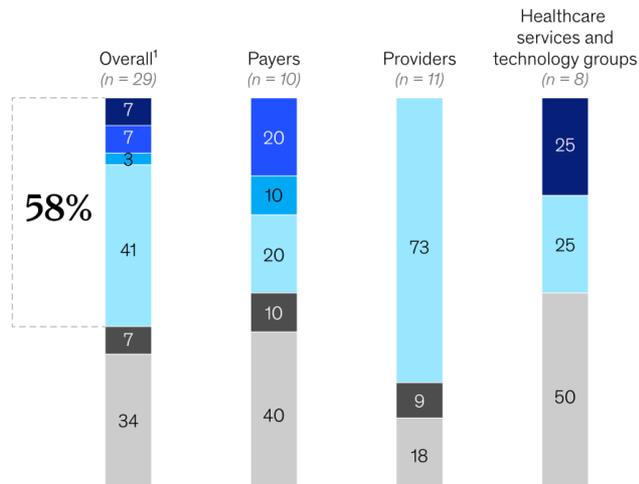
The ROI for gen AI

As with any investment, it's critical for stakeholders to be able to realize the value that gen AI promises. A measurable positive impact serves as strong reinforcement for continued and expanded use and investment. While the number of respondents who have implemented gen AI is small, among those who have, most have not yet calculated the ROI or are waiting on measurable results. But about 60 percent of those who have implemented gen AI solutions are either already seeing a positive ROI or expect to.

Among the respondents who report implementing gen AI, few have quantified its impact, but nearly 60 percent believe it yields a positive ROI.

ROI of use cases for healthcare organizations implementing generative AI (gen AI), by organization type, % of respondents

- >4x
- 2-4x
- <2x
- Positive ROI; awaiting measurable impact
- Negative ROI; awaiting measurable impact
- Unclear value potential



¹Figures do not sum to 100%, because of rounding.
Source: McKinsey US survey on gen AI in healthcare, Mar 11-13, 2024





WHAT ARE THE TRENDS?

GENERATIVE AI'S VAST SCOPE

Gen AI's vast scope

Gen AI may create tremendous value in areas that could fundamentally improve patient experience and streamline operations. Specifically, clinician and clinical productivity is viewed by most respondents as an area where gen AI may have the highest value. Furthermore, expectations for gen AI's potential in applications to improve patient and member engagement and experience, administrative efficiency and effectiveness, and quality of care and delivery indicate a diffusion of gen AI interest beyond clinical uses into areas that improve overall patient care interactions.

Generative AI is thought to hold the highest potential value in improving clinical productivity as well as patient engagement and experience.

Areas believed to benefit the most from generative AI (gen AI), % of respondents (n = 100)



Source: McKinsey US survey on gen AI in healthcare, Mar 11–13, 2024

McKinsey & Company





WHAT ARE THE TRENDS?

HURDLES TO SCALE UP

Hurdles to scale up

Risk concerns and considerations top the list of scale-up challenges faced by surveyed leaders, regardless of whether they work at a payer, provider, or HST company. This is likely due to the untested nature of the technology, the investment needed to build capabilities, and uncertainty around regulations. It signals the importance of governance and mitigation strategies to tackle the range of risk issues—from privacy to clinical outcomes—to ensure regulatory compliance and excellence in care. After risks, the next most prevalent roadblocks indicated by respondents are insufficient capability, data and tech infrastructure, and proof of value. This demonstrates healthcare organizations' limited tech readiness to deploy gen AI solutions and also to validate its capabilities.

Risk concerns and considerations was the top challenge among healthcare organizations pursuing generative AI.

Biggest challenges for organizations implementing or pursuing generative AI, % of respondents



McKinsey US survey on gen AI in healthcare, Mar 11–13, 2024

McKinsey & Company





WHAT'S ON THE HORIZON?



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POTENTIAL USE CASES

GENERATIVE AI IN HEALTHCARE

Generative AI Has Potential Use Cases Across All Health Care Segments



Pharmaceutical firms

- ✓ Accelerated drug discovery and design
- Clinical-trial planning and execution
- ✓ Precision medicine therapies



Providers

- ✓ Patient screening and on-demand, personal care
- ✓ Automated document processing
- Medical image recognition
- ⓘ EHR interoperability



Payers

- ⓘ Preventative health care through predictive models
- Automation of claim processing



Medtech

- Generative product design
- ⓘ Diagnostic image enhancement and analysis
- Supply chain risk identification and process augmentation



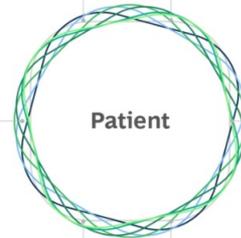
Services and operations

- ⓘ Synthetic-data generation
- ⓘ Inventory tracking and restocking
- ⓘ Data sharing/interoperability
- Generative AI cloud services



Public-health agencies

- Public-health surveillance
- ⓘ Resource allocation and utilization



✓ Validated ○ Early stage ⓘ Conceptual

Source: BCG analysis.





MOBILE DEVICES + AS MEDICAL DEVICES

Mobile phone, smart watches,
and wearable technologies
frequently feature health
monitoring applications.





ONLINE DOCTOR VISITS

Test results and other diagnostics can be interpreted for patients and family members in real time using generative AI.



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THANK YOU

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