

99% of Life Sciences organizations are embracing AI. Are you?

Life Sciences organizations are enthusiastically embracing AI, but concerns flagged over talent, skills, and data quality point to the limitations of taking an in-house approach.



Life sciences organizations are taking aggressive steps to make sure they don't fall behind in the race to achieve benefits from the adoption of artificial intelligence (AI) technology. A new survey of technology decision-makers at a broad range of organizations in life sciences segments reveals just 1% have not implemented AI in any area of quality and regulatory processes, while 99% are in various stages ranging from pilots to full integration.

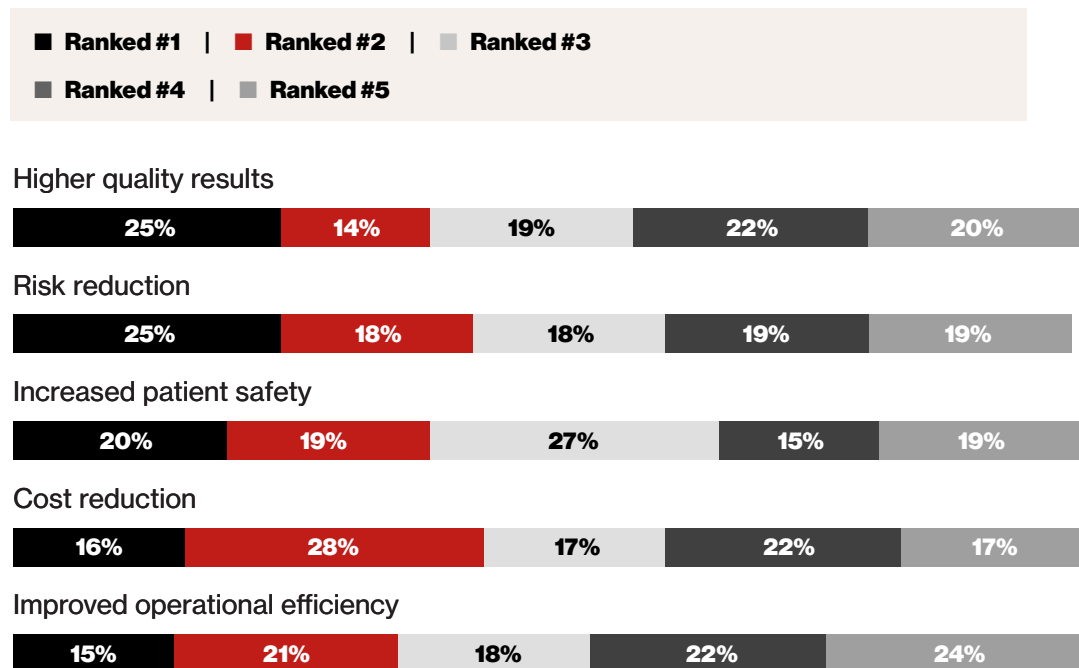
The survey findings demonstrate how widely organizations are

embracing AI. Achieving higher quality results and reducing risk were equally ranked as the most important outcomes they are pursuing.

The survey, by Foundry and Honeywell Life Sciences, polled 109 senior decision-makers (director level or higher) in IT technology-related roles at organizations engaged in pharma, medical devices, biotech, or clinical research. Participants provided insight on their anticipated outcomes and the challenges of AI adoption for quality management and regulatory compliance.

Figure 1 | Higher quality results and risk reduction are ranked as the most important outcomes of adopting AI-driven solutions

Important potential outcomes of adopting AI-driven solutions



SOURCE: FOUNDRY

AI adoption rapid for some, just starting for others

Despite the almost universal embrace of AI, it's clear that some organizations are forging ahead more rapidly, either due to greater readiness or the ability to overcome obstacles that are slowing progress for many others.

Just over one-third indicate they have fully integrated the technology across quality and regulatory processes. The remainder are almost evenly split between those who are using AI for specific processes and those who are just at the pilot project stage. Many are undoubtedly moving cautiously as they navigate the complexity of implementing AI amid the complexity of regulatory and quality systems and lack of clear guidance from regulators.

While cost reduction trailed for top ranking overall, it was foremost for pharmaceutical organizations. Bio-tech and clinical research organizations understandably placed higher quality results at the top of their lists. Medical devices and diagnostics companies accustomed to rigorous risk management requirements, such as the ISO 14971¹, were more intent on risk reduction and increased patient safety.

Corrective and preventive action-oriented

Survey respondents indicate a high degree of agreement in the use cases they have implemented, planned, or are interested in. Evaluation of corrective and preventive action (CAPA) effectiveness has already been implemented by 28%, followed closely by improved signal detection of high-risk events, and identifying quality events to detect recurrence or avoid duplication of investigations.

Almost one-third of larger companies are using AI for proactive CAPA checks, compared to 23% of smaller organizations, and are also ahead (30% to 15%) in applying the technology to auto-categorize complaints. Auto-categorization is



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Figure 2 | More than one-quarter (28%) report use of AI to evaluate CAPA effectiveness; use of AI to improve signal detection is planned by 37%

Use cases for AI in quality or regulatory functions

■ In use | ■ Planned | ■ Of potential interest | ■ No value

Proactive CAPA effectiveness checks (by evaluating completed/proposed CAPA)



Identify related quality events to detect recurrence or avoid duplication of investigations.



Improve signal detection (detection of high-risk events)



Proactive audit readiness (by auto-reviewing prior audits, actions and findings)



Complaints auto-categorization (by type, reportability and/or severity)



Minimize regulatory submission risk (learn from prior regulatory submissions and rejections)



SOURCE: FOUNDRY

in use, planned, or of interest at 46% of pharmaceutical companies, while 53% of biotech and clinical research organizations say the same for identifying related quality events.

“Making existing processes and systems more effective and more efficient, unsurprisingly, are top of mind right now, but we’re at the beginning of the implementation cycle and only scratching the surface of what is possible,” says Fabrizio Maniglio, Director, Industry and Business Development with Honeywell. “With

new and cutting-edge AI applications we can start to solve problems that were not solvable before.”

Top challenges

Technological readiness (48%) and data accessibility and quality (47%) are the top factors impacting timelines for AI adoption. However, among those furthest along in adoption, who have already integrated AI across systems, 52% rank data access and quality highest. Those numbers highlight the

dependence of AI on data as the essential fuel for achieving results, and the complexity in realizing the potential of technology adoption.

Cultural issues, ROI concerns, budget constraints, and the regulatory environment are also significant concerns, each cited as key factors by more than 40% of respondents. This underscores why organizations must first understand the desired outcomes and how to measure success before determining if AI is the right tool to deliver them. Still, almost all respondents say they are “ready to go” or somewhat ready to support AI implementation across areas such as data management issues and in-house skills.

While 79% of those who have fully integrated AI across systems are confident in their infrastructure readiness to scale, more than half of those who have yet to achieve that level are not – indicating they stand to fall further behind in the race for AI adoption. Confidence must be conditioned on the likelihood that the scale required to keep pace with AI may elude even the most advanced companies that do not sufficiently focus on infrastructure challenges.

Boosting AI readiness

The survey indicates those who are most advanced are in position to benefit from continued rapid adoption of AI, likely because they invested earlier, learned from prior missteps, and developed best practices to foster continued success.

With the unprecedented pace of AI innovation, it is imperative effective decision-making is based on actionable insights, best practices and quality management systems. Those seeking to catch up may benefit from partners who can provide the infrastructure, platform and solutions to deliver improved results, enabling them to devote resources to core competencies that, regardless of segment, must ultimately focus on better patient outcomes.

Learn more about
AI-enabled applications
for Life Sciences
www.trackwise.com

1 [ISO 14971:2019\(en\), Medical devices – Application of risk management to medical devices](#)