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The road to responsible AI adoption in life sciences

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Introduction

Artificial intelligence (AI) has long been regarded as a pivotal catalyst for innovation within life sciences organizations, particularly in R&D domains. However, the advent of generative AI (GenAI) has broadened the horizon, offering unprecedented opportunities and scalability that extend well beyond R&D, making AI technologies accessible even to those without a background in data science. This evolution is propelling organizations to explore AI's potential across new fronts, from speeding up drug discovery and predicting clinical trial outcomes with greater accuracy to tailoring personalized medicine with finer precision.

According to the KPMG 2024 CEO Outlook survey, a striking 64 percent of life sciences executives now prioritize AI investments, underscoring the technology's integral role in future advancements. Yet, as enthusiasm for AI's potential grows, so does the urgency for its responsible adoption within this highly regulated, patient-centered industry.

For example, the U.S. Food and Drug Administration (FDA) has issued guidelines for AI and machine learning (ML) in medical devices, emphasizing the importance of safety and effectiveness while fostering an environment conducive to technological advancements. Additionally, in January 2024 the FDA released an updated Center for Drug Evaluation and Research (CDER) draft guidance agenda that included prioritizing the release of "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision Making for Drug and Biological Products" for clinical/medical.[1] Similarly, the Health Insurance Portability and Accountability Act (HIPAA) applies to patient data used in AI contexts where covered entities and business associates are involved, further solidifying the foundation for innovative applications in a patient-centric industry.

As AI technologies continue to proliferate, the emerging regulatory landscape is not just a series of hurdles but a framework that supports responsible innovation. Leaders in the life sciences sector must prioritize the integration of AI with regulatory frameworks, risk management strategies, and their own innovation strategy. This dual focus on groundbreaking technologies and rigorous governance ensures that life sciences leaders can pursue their innovation strategies with confidence, knowing that trust in AI systems is bolstered through continuous adherence to responsible principles.

This paper delves into the various applications of AI in life sciences, the evolving regulatory landscape, and practical steps for managing risk and fostering trust within your organization. Further, this paper outlines a strategic roadmap for the ethical integration of AI adoption in life sciences, emphasizing how regulatory compliance can be a catalyst for innovation.

[1] "Artificial Intelligence for Drug Development," U.S. Food & Drug Administration, October 31, 2024

An unfolding landscape of impact and challenges

As AI surges into every corner of the life sciences field, its role is expanding in various areas from research to patient care. AI can harness vast amounts of data with predictive analytics, which uses that information to predict future events—for example, to assess patients' risk levels, make differential diagnoses, chart the likely progression of disease, and gauge effectiveness of treatments. Increasingly essential in drug development, ML provides hypotheses about potential drug targets, how novel compounds may behave, possible side effects, and new applications for existing drugs.

GenAI, in particular, has the potential to deliver significant productivity gains, streamline operations, cut costs, and speed up the delivery of treatments. Organizations are already using GenAI to improve drug development and design clinical trials. Additionally, KPMG supports organizations in leveraging GenAI to respond to health authority inquiries, automate the creation of product labeling, and create standardized operating procedures.

In manufacturing, GenAI can be utilized to monitor supply chain risks, forecast demand, and manage relationships with suppliers. Moreover, it can help increase accuracy, speed, and cost-effectiveness for corporate functions including, but not limited to, finance, procurement, legal, human resources, and IT.

Yet for all of the promise of AI in life sciences, important challenges have caused organizations to pause to consider the implications of its adoption. Many applications depend on large datasets, which may contain sensitive patient information—known as protected health information (PHI)—and it can be difficult to ensure that patients understand and consent to how their data may be used.

There are also concerns about how to provide inclusive access to AI-driven innovations. Transparency and explainability of "black box" algorithms are also challenging, both for meeting regulatory requirements and explaining to patients how decisions about their care are being made. A lack of explainability can also hinder the ability to identify and correct errors in AI-enabled processes today, or even potential decision-making of autonomous AI in the far future.

Accelerating research while considering constraints

In the lab of Jin Kim Montclare, professor of chemical and biomolecular engineering at New York University, AI greatly accelerates the process of designing and customizing artificial proteins for applications that include targeting human disorders, drug delivery, and tissue regeneration. Using ML, the scientists can solve problems that previously would have required a labored, trial-and-error process of creating a large number of new proteins and then testing each one to see whether it can accomplish a particular task. "Machine learning lets us access a diverse library of sequences and then generate a subset of proteins to test that have the properties and behaviors we're looking for," says Montclare. "That saves us from wasting our time rationally trying to design proteins."

As this work moves forward, Montclare and her team are beginning to consider what they need to do to comply with emerging regulatory requirements. "There are FDA standards for safety and efficacy that are essential, and we need to be able to show what we've done," she says. "When we work with ML, we set the parameters. We think about the data we're looking at, what we're trying to accomplish, and the possible restrictions. We have to make sure we understand what ML is doing."

The potential for AI models to perpetuate or amplify biases in training data is another major issue and can lead to unfair or inaccurate outcomes for underrepresented populations. For example, women of childbearing potential were broadly excluded from early-phase clinical trials under a 1977 FDA guideline, a restriction that was not reversed until 1993.

Consequently, there is a critical lack of sex-specific safety and metabolic data on female patients from this era, leaving historical datasets heavily skewed toward male biology.

Specifically, key challenges include:

- Quantity and quality of data training the model
- Data privacy concerns
- Equitable access to AI-driven healthcare innovations
- Transparency of AI usage and decision-making process

Actionable insights and recommendations:

- **Enhance data governance:** Implement rigorous data anonymization, de-identification, and access control techniques to safeguard patient data.
- **Address algorithmic bias:** Use diverse and representative datasets for training AI models and conduct regular bias assessments to identify and mitigate harmful bias and discrimination.
- **Prioritize transparency:** Develop clear documentation and protocols to explain AI decision-making processes to stakeholders, including patients, as well as indicate when interacting with a system, process, or tool that is leveraging AI.

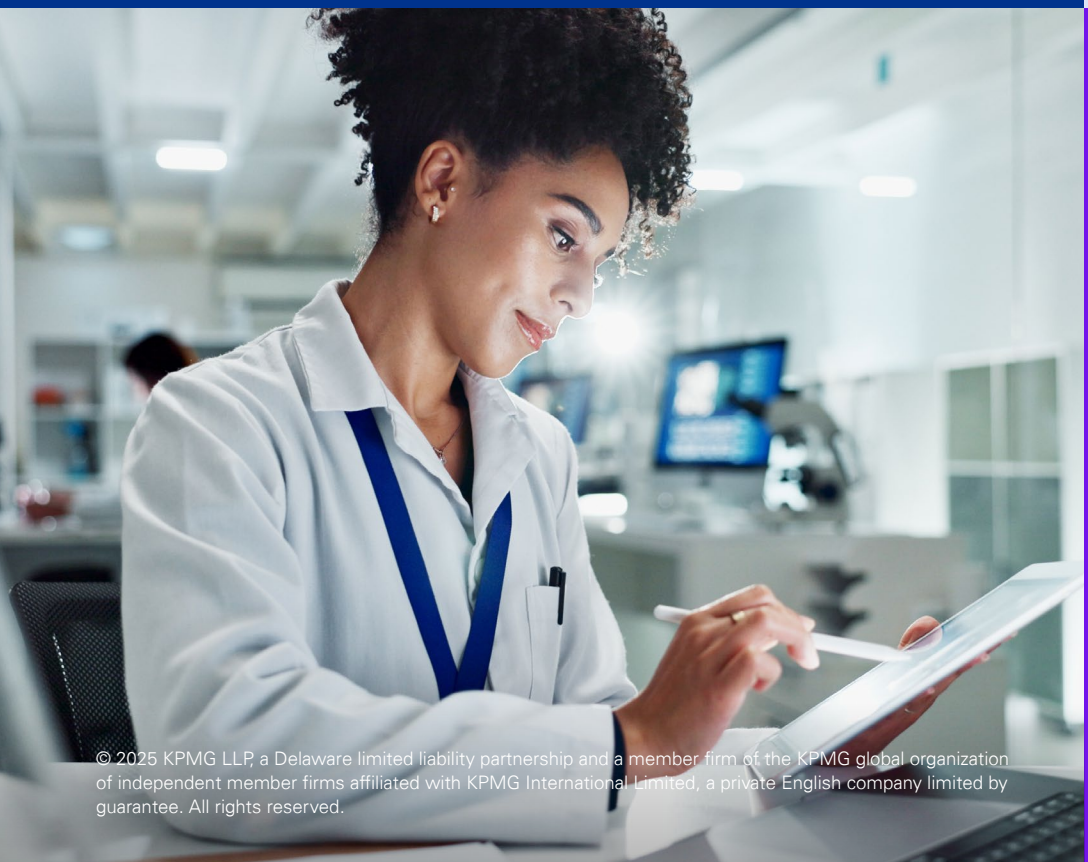
GenAI was utilized in the creation of this image

Ensuring responsible innovation

Like other life sciences organizations, Johnson & Johnson (J&J) increasingly depends on wide-ranging AI applications for research and development and other uses. Jessica Kahl-Winter, vice president of global audit and assurance, believes that AI is a game-changer for everyone in the organization. "It's revolutionizing the way we work, think, and solve problems at a level none of us has ever seen before," Kahl-Winter says. "Within life sciences, it holds tremendous potential to advance human health on a global scale."

Charged with advising and ensuring that AI is used responsibly and compliantly, Kahl-Winter has been involved as J&J creates guardrails for how the technology is deployed and developed. "Very early, our company established rules of the road about what we expect responsible use to look like," she says. "We also created a cross-functional group to oversee AI's development that made sure that everyone—data science, tech, legal, compliance, and our business leaders—had a seat at the table."

Kahl-Winter says that the challenge is to control what's happening with AI without impeding innovation unnecessarily. That means not only considering current uses but looking ahead both to future advancements of AI as well as evolving regulatory requirements. "This is becoming a team sport," she says. "We're creating an environment in which we are developing strong digital acumen across all our employees so that everyone can be involved in making sure AI develops responsibly and to its full potential."



> **"We're creating an environment in which we are developing strong digital acumen across all our employees so that everyone can be involved in making sure AI develops responsibly and to its full potential."**
>
> — Jessica Kahl-Winter, Vice President of Global Audit and Assurance, Johnson & Johnson

The evolution of regulatory and compliance frameworks

As life sciences organizations continually ramp up their use of AI, leaders face a still-developing web of state, national, and global regulation. Several US states have begun setting rules for AI, with Colorado enacting the first comprehensive framework for regulating "high-risk AI systems."

In California, a bill to regulate AI was vetoed in September 2024 by Governor Gavin Newsom.[2] The legislation, which would have applied only to AI systems that cost at least $100 million to develop, would have required testing to determine whether they would likely lead to mass death, endanger public infrastructure, or enable severe cyberattacks. The contention around the bill reflects the challenges many organizations are facing to determine the proper balance between risk and innovation. Life sciences organizations will need continued diligence to understand the impact of growing AI regulation, and legal and compliance teams should be fully engaged to ensure all jurisdiction specific requirements are met.

Additionally, recent AI-related guidance from the FDA, alongside the new draft guidance, emphasizes the need to leverage risk-based credibility assessment frameworks to establish AI as trustworthy. The current administration's executive orders, aimed at establishing American leadership in AI and rescinding the previous administration's Executive Order on AI (October 2023), do not diminish these clinical safety requirements. On the contrary, this shift toward deregulation further highlights the FDA's independent role in maintaining strict, risk-based credibility standards to ensure patient safety in medical AI.

These developments signal a continued need for life sciences organizations to remain diligent in understanding and navigating regulations across various jurisdictions. By adopting a risk- and framework-based approach, organizations can foster innovation and progress with AI use cases in a trusted manner.[2]

The European Union AI Act

The European Union AI Act, in force since August 2024, may be the most fully fleshed out regulatory framework for the global deployment of AI, although its primary focus is on the EU and its member states. The EU AI Act introduces a risk-based approach that considers whether AI applications pose minimal risk, limited risk, or high risk. There's also a "prohibited" category. Most AI and GenAI use cases are likely to be subject primarily to transparency requirements, although classification under the Act ultimately depends on the intended use and deployment context. AI applications used in certain regulated settings—including healthcare and medical device use cases—may be considered high risk, and a chief focus of the legislation is to make it easier for individuals to be aware of what happens with their data and to make sure it is used ethically.

The Act requires organizations to take stock of current AI use cases and to adhere to rules about data and data governance, including that data must be high quality and free from errors, representative, and relevant to the AI's purpose. Potential biases must be assessed and mitigated, and organizations have to establish processes to manage data throughout the data's lifecycle. There are rules for technical documentation, transparency, and human oversight, heavy fines for violations, and non-compliant AI systems may be banned in the EU.

The EU AI Act leverages two previously enforced regulations specific to the life sciences sector—medical device regulation (MDR) and in-vitro diagnostic regulation (IVDR). A medical device using AI may be subject to the rules of the EU AI Act as well as of MDR, IVDR, or perhaps all of the above.

[2] The New York Times, "California Governor Vetoes Sweeping A.I. Legislation," Cecilia Kang, September 29, 2024

General Data Protection Regulation

Another earlier EU regulatory effort—General Data Protection Regulation, or GDPR—required major compliance efforts from life sciences organizations, which were disproportionately affected because of the amount and significance of PHI in those organization's operations. Those efforts mean that for many organizations, the new law may require only a gap assessment to leverage existing processes to comply with the additional requirements of the EU AI Act.

The impact of AI and ML on the FDA's regulation of software as medical device (SaMD) requirements is another increasing focus for life sciences organizations that design and manufacture medical devices. For example, the traditional assumption that devices will remain static after approval doesn't apply to those that use adaptive algorithms and continuous learning to become "smarter" and more effective. That reality has led the FDA to introduce a Predetermined Change Control Plan (PCCP) to allow for prespecified improvements and algorithm changes without sending a device back for premarket review.

A requirement for continuous monitoring of AI/ML device performance means that organizations must implement extensive postmarket surveillance, and the need for transparency and explainability has resulted in new rules for documentation of model architecture, training data, and decision-making processes.

ISO 42001

As the regulatory landscape for AI continues to evolve, organizations in the life sciences sector can benefit from adopting international standards to demonstrate their commitment to responsible AI practices through an objective third party. ISO 42001, a comprehensive international standard for AI management systems, provides such a framework for organizations to establish, implement, maintain, and continuously improve their AI governance processes.

While ISO 42001 can help organizations meet many of the requirements of the EU AI Act, it is important to note that it may not directly address all specific provisions of the legislation. To ensure full compliance with the EU AI Act, organizations may need to supplement ISO 42001 certification with additional measures, such as conducting specific risk assessments, developing detailed documentation, and implementing additional controls as required by the act.

Compared to another well-known assurance standard, such as a SOC certification, ISO 42001 provides a globally recognized framework that can be applied to organizations operating in various jurisdictions. By combining ISO 42001 certification with a tailored approach to address the requirements of the EU AI Act or other AI-focused regulations, life sciences organizations can demonstrate their commitment to responsible AI practices and gain a competitive market advantage.

Even as these current regulatory efforts are put into place, a rapidly evolving focus on fairness, data privacy, cybersecurity, and resilience will add to the complexity for life sciences organizations as they attempt to ensure compliance throughout their organizations.

Actionable insights and recommendations:

- **Stay informed on regulations:** Regularly monitor updates in AI regulations at the local, national, and international levels.
- **Implement compliance strategies:** Develop compliance strategies that align with regulatory requirements, such as the EU AI Act, and ensure continuous adherence through audits and monitoring systems.

The road to compliance and trust

In our discussions with key business and commercial leaders in life sciences, we have found that many, while understanding the significance and complexity of current and future AI regulatory requirements, don't yet have fully developed strategies to ensure compliance. Their uncertainty also can lead to concerns that regulations could hinder progress.

To ensure that organizations can continue to use AI in innovative ways while complying with current and future regulations, life sciences organizations must take steps to address concerns about data privacy, cybersecurity vulnerabilities, algorithmic bias, model reliability, and data integrity. Addressing data privacy requires implementing techniques for data anonymization and de-identification, and strict access controls and policies for data governance. Avoiding algorithmic bias means using diverse and representative data sets to train AI models, while maintaining model reliability and data integrity entails rigorous testing and validation procedures, and regular, intensive data audits.

AI can play a significant role in improving operational compliance and automating regulatory submissions. AI-driven tools can analyze vast amounts of data to ensure that all regulatory requirements are met, reducing the risk of human error. These tools can also streamline the process of regulatory submissions, making it faster and more efficient. AI's ability to process and interpret large datasets allows organizations to stay updated with the latest regulatory changes, ensuring continuous compliance. AI-supported audits provide real-time compliance updates and can identify potential issues, reducing the time and resources traditionally spent on manual audits.

Actionable insights and recommendations:

- **Conduct comprehensive audits:** Regularly audit AI systems for compliance with data privacy policies and regulatory requirements.
- **Develop ethical standards:** Establish consensus on ethical considerations and embed them into AI governance structures.
- **Facilitate ongoing training:** Provide continuous training to employees on AI capabilities, limitations, and ethical use.

Gauging the status of AI adoption

Preparing life sciences organizations to meet regulatory requirements while establishing trust in their AI systems begins with a comprehensive inventory of internally developed and third-party AI applications, including "shadow AI" applications. Understanding the vulnerabilities of AI currently in use is crucial for assessing the risks posed by the organization's complete AI footprint.

A leading practice to address these challenges is establishing an AI governance council. This body should comprise cross-functional expertise from information technology, cybersecurity, legal, privacy, compliance, third-party risk, enterprise risk management, finance, supply chain, and internal audit. The primary mandate of the AI council is to set the AI governance strategy and supporting principles, review proposed AI usage in alignment with the organization's risk appetite, ensure regulatory compliance is properly addressed, provide acceptable usage guidelines, and document enterprise risks.

While many organizations excel at setting up an initial governance framework to scrutinize proposed AI initiatives, there is often a gap in the post-implementation phase. Strengthening postmortem reviews to confirm that AI projects or programs were developed in accordance with regulatory requirements and align with the approved business case is essential. This ensures continued regulatory compliance and alignment with business objectives, thereby enhancing trust in AI systems.

To support the AI governance council and AI development teams, it is crucial to utilize or establish a responsible AI framework that considers the entire AI development lifecycle. This framework should align with regulatory requirements, ethical considerations, and operational best practices, enabling consistent and sustainable practices and ensuring trust in AI systems.

Shadow AI

Shadow AI refers to artificial intelligence systems, applications, or projects that are developed and deployed within an organization without explicit approval, oversight, or awareness from the central IT, compliance, or governance teams. These unauthorized AI initiatives often arise from individual departments or teams seeking quick solutions or innovation, bypassing standardized policies and procedures. While Shadow AI can drive rapid innovation and address specific business needs, it also introduces significant risks, including data privacy vulnerabilities, security gaps, compliance breaches, and potential misalignment with the organization's strategic objectives. It is crucial for organizations to identify and manage Shadow AI to ensure overall integrity, security, and regulatory compliance.

Actionable insights and recommendations:

- Define an AI governance council with roles and responsibilities that support capabilities.
- Define the operating model strategy.
- Evaluate current compliance and policy requirements.
- Create and communicate an AI governance policy and supporting standards/procedures.
- Develop user awareness training for responsible AI usage.
- Update contractual requirements to acknowledge AI usage and address third/fourth-party risk.
- Establish a standard process for AI intake and maintain a comprehensive inventory of existing AI and ML systems.
- Use a responsible framework to help evaluate your existing gaps and areas for development.

KPMG Trusted AI

KPMG has developed its Trusted AI framework to help organizations understand and evaluate their current and future AI applications, assess how those systems will be classified and governed in the emerging regulatory environment, and enhance risk management and compliance. Within this framework, trust becomes an essential element of AI development through establishing AI governance bodies and strategies, evaluating the risk-versus-value of each AI application and system, and enabling ongoing improvements.

Values-led

Privacy: AI solutions should comply with applicable privacy and data protection laws and regulations.

Sustainability: AI solutions should be energy efficient, reduce carbon emissions, and support a cleaner environment.

Fairness: AI solutions should reduce or eliminate bias against individuals, communities, or groups.

Human-centric

Transparency: AI solutions should include responsible disclosure and be transparent.

Explainability: AI solutions should answer questions of how and why a conclusion was drawn.

Accountability: Human oversight and responsibility should be embedded across the AI lifecycle to manage risk and comply with applicable laws and regulations.

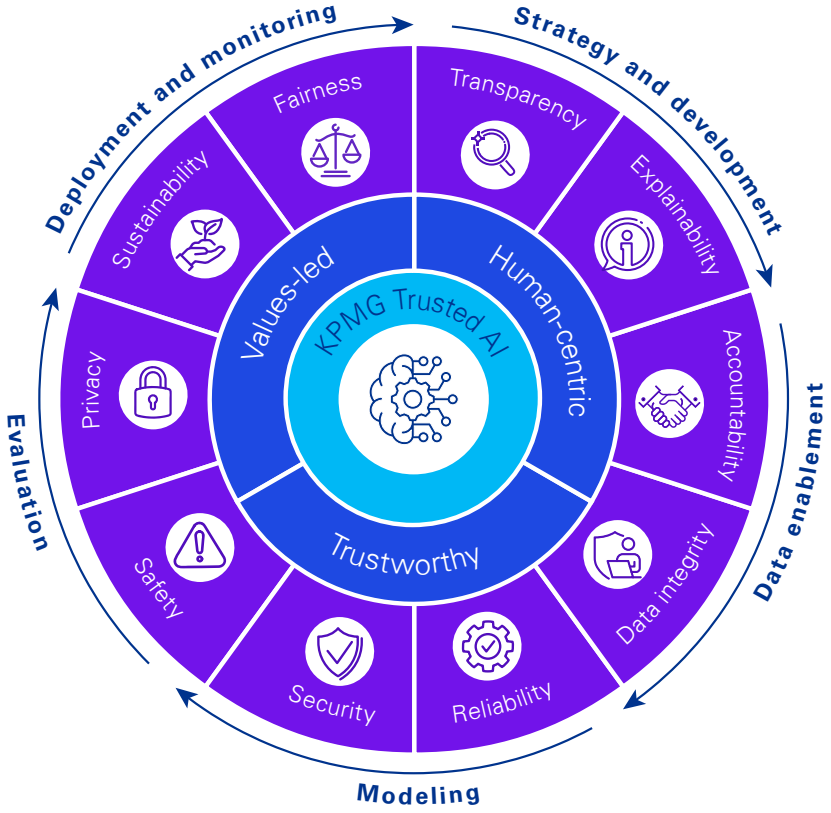
Trustworthy

Data Integrity: Data used in AI solutions should be acquired in compliance with applicable laws and regulations, and assessed for accuracy, completeness, appropriateness, and quality.

Reliability: AI solutions should consistently operate in accordance with their intended purpose and scope.

Security: Robust and resilient practices should safeguard AI solutions against bad actors and misinformation or adverse events.

Safety: AI solutions should be designed and implemented to safeguard against harm to humans and property.

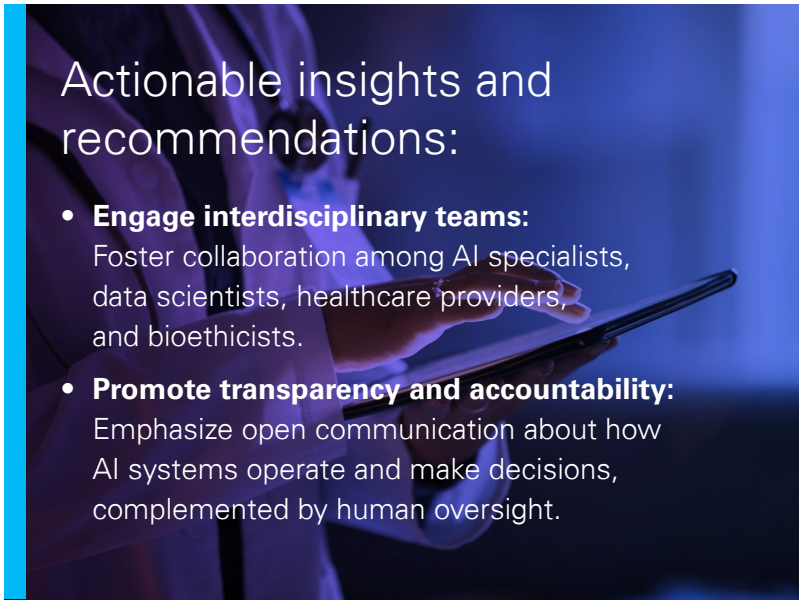


A values-led, human-centric, trustworthy framework

Frameworks for establishing trust in AI will vary according to the needs of each organization. In life sciences, a framework may have several specific, unique aspects related to working with patients, healthcare providers, and treatments. These may include:

- Validation and rigorous testing of algorithms using extensive clinical trials and real-world evidence
- Aligning AI development and deployment with current and future regulations
- Prioritizing patient safety by implementing mechanisms to detect and mitigate AI risks
- Using clinical and patient data responsibly and ethically and obtaining all appropriate consents
- Continually assessing the balance between risks and benefits of AI applications
- Promoting interdisciplinary collaborations among AI specialists, data scientists, healthcare providers, and bioethicists in developing and deploying AI systems
- Involving patients in the development process whenever feasible
- Continuous training about effective and permissible use of AI tools

As an example, KPMG has developed its Trusted AI framework to help organizations understand and evaluate their current and future AI applications, assess how those systems will be classified and governed in the emerging regulatory environment, and enhance risk management and compliance. Within this framework, trust becomes an essential element of AI development through establishing AI governance bodies and strategies, evaluating the risk-versus-value of each AI application and system, and enabling ongoing improvements through future iterations of those systems.



Actionable insights and recommendations:

- **Engage interdisciplinary teams:** Foster collaboration among AI specialists, data scientists, healthcare providers, and bioethicists.
- **Promote transparency and accountability:** Emphasize open communication about how AI systems operate and make decisions, complemented by human oversight.

The KPMG Trusted AI framework is based on these three foundational principles—***values-driven, human-centric, and trustworthy***—to promote integrity, fairness, and effectiveness. These principles, in turn, underpin actions that life sciences organizations can take to ensure that their use of AI builds trust and supports organizational goals for the technology.

1 Enabling data quality and safety

The data that drives ML and other AI applications must be high quality and representative, tested for accuracy, securely stored, and protected from cyber threats. Employee training, penetration testing, and procedures for responding to risks are essential.

2 Enhancing ethics and compliance

Life sciences organizations need to reach consensus about ethics and compliance considerations and embed them in their systems and governance. Testing for potential bias and discrimination and adjusting systems to eliminate those problems must be accompanied by regular compliance monitoring, audits, and risk assessments. Establishing these guardrails and procedures now will help prepare for emerging regulatory requirements.

3 Promoting transparency and accountability

Solving the black box problem is crucial for building trust, and life sciences organizations need to emphasize the importance of being open about how AI systems operate and make decisions. Human oversight is also critical in helping ensure that issues in these areas are identified and addressed.

4 Driving continuous refinement

AI applications are designed to learn, improve, and adapt to the constant changes across the life sciences landscape. That reality requires organizations to build in processes for continuous refinement to ensure that ongoing technological innovation not only maintains trust in how AI is used but also delivers benefits throughout the organization.

Values-driven

We implement AI as guided by our values. They are our differentiator and shape a culture that is open, inclusive, and operates to the highest ethical standards. Our values inform our day-to-day behaviors and help us navigate emerging opportunities and challenges.

Human-centric

We prioritize human impact as we deploy AI and recognize the needs of our clients and our people. We are embracing AI to empower and augment human capabilities—to unleash creativity and improve productivity in a way that allows people to reimagine how they spend their days.

Trustworthy

We will adhere to our principles and the ethical pillars that guide the how and why we use AI across its lifecycle. We will strive to ensure our data acquisition, governance, and usage practices uphold ethical standards and comply with applicable privacy and data protection regulations, as well as any confidentiality requirements.

As a practical use case, with the KPMG Trusted AI framework in action, please refer to the below example around drug discovery and development

Use case:
Machine learning models can analyze vast chemical and biological datasets to predict potential drug candidates and identify novel drug targets. AI can simulate how different compounds interact with human proteins, thereby accelerating the initial discovery phase and optimizing lead compounds.

Example:
A pharmaceutical company can leverage AI to reduce the time required for identifying potential drugs to fight diseases, potentially cutting down the drug discovery phase timing significantly.

Applying Trusted AI principles:

Fairness, privacy, and data integrity
Confirm that the training datasets are diverse, representative, and devoid of harmful biases. Regularly audit data sources for quality and relevance.

Transparency and explainability
Document and explain the decision-making processes of AI models to stakeholders.

Safety and reliability
Perform extensive validation and testing using clinical trials and real-world evidence to ensure safety and efficacy.

Accountability and explainability (regulatory alignment)
Align AI development processes with FDA and international guidelines for pharmaceutical innovation.

Conclusion

As regulation of this rapidly evolving technology continues to develop, implementing a responsible AI framework can enable life sciences organizations to take advantage of AI's promise for developing breakthrough products and more efficient operations while also meeting ethical and compliance standards. Taking steps now to build trust in AI while managing its risks can help ensure progress and success in a highly competitive, heavily regulated, and patient-centered industry.

The integration of AI within the life sciences sector presents unparalleled opportunities for innovation including, and not limited to, drug discovery, clinical trials, and patient care. However, the journey toward harnessing AI's full potential is paved with the necessity for ethical governance, compliance, and robust risk management strategies. To manage these challenges effectively, life sciences organizations are encouraged to adopt a framework that exemplifies responsible AI implementation. As an example, the KPMG Trusted AI framework provides a comprehensive model to help you align AI adoption with the rigorous demands of regulatory compliance, ethical considerations, and the building of trust within AI systems.

By emphasizing data protection, actively addressing algorithmic bias, ensuring transparency, and fostering interdisciplinary collaboration, life sciences organizations can position themselves at the forefront of responsible innovation. This strategic approach not only meets the evolving landscape of regulations but also secures trust in AI applications. Ultimately, it propels the sector toward achieving its dual aims of enhancing patient outcomes and optimizing operational efficiencies, affirming the life sciences industry's role at the intersection of cutting-edge technology and patient-first healthcare.

How KPMG can help

In the rapidly emerging field of responsible AI, KPMG professionals design, build, deploy, and use AI technology solutions ethically and accountably to deliver value confidently. Our Trusted AI framework, along with our extensive experience in regulation, tax transparency, audit innovation, risk management, security, privacy, and other critical areas, is invaluable in this domain. As an initial adopter, our multibillion-dollar investment in AI capabilities enables us to leverage AI's benefits, enhancing client engagements and improving employee experiences in a responsible, trustworthy, and safe manner. We can help your organization:

- Perform a rapid assessment of your AI readiness
- Establish a Trusted AI framework
- Implement controls and model testing
- Explore the latest AI use cases

Contact us

Authors

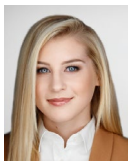
Bryan McGowan
Principal, Global Trusted AI Leader
KPMG LLP (US)
bmcgowan@kpmg.com

Jason Glantz
Principal, Advisory
Life Sciences
KPMG LLP (US)
jglantz@kpmg.com

Dipan Karumsi
Principal, Advisory
Life Sciences
KPMG LLP
dkarumsi@kpmg.com

Katie Boswell
Managing Director, Cybersecurity and Tech Risk
KPMG LLP (US)
katieboswell@kpmg.com

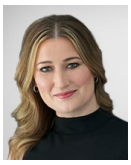
Jordan Seiferas
Managing Director, Data & Analytics
Life Sciences
KPMG LLP (US)
jseiferas@kpmg.com



Kristy Hornland
Director, Cybersecurity & Tech Risk
KPMG LLP (US)
khornland@kpmg.com

René Krause
Senior Manager, Regulatory Advisory
KPMG in Germany
renekrause@kpmg.com

KPMG Global Life Sciences Leaders



Kristin Pothier
Principal, US Life Sciences Sector Leader
Global Deal Advisory and Strategy Healthcare and Life Sciences Leader
KPMG LLP (US)
kpothier@kpmg.com

Liz Claydon
Partner, Global Life Sciences Sector Leader
KPMG LLP (UK)
liz.claydon@kpmg.co.uk

Jon Haynes
Partner, EMA Life Sciences Sector Leader
KPMG LLP (UK)
jon.haynes@kpmg.co.uk

Peter Liddell
Principal, ASPAC Life Sciences Sector Leader
KPMG in Singapore
peterliddell1@kpmg.com.sg

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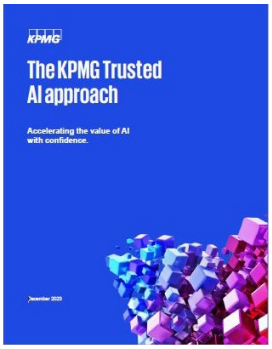
Recommended reading:

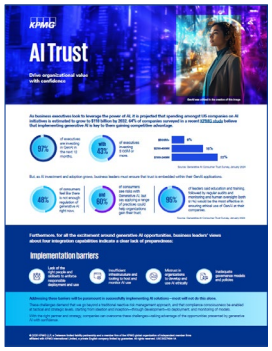
The importance of Trusted AI in healthcare



The KPMG Trusted AI approach

EU AI Act: Compact practical guide for the life sciences sector

Focus US: Navigating the EU Artificial Intelligence Act



AI Trust Services

An Illustrative AI Risk and Controls Guide

The guide to AI risks and underlying control considerations for risk, technology, compliance, and legal leaders

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