IQVIA TECHNOLOGIES

White Paper

AI in Life Science Quality Management and Regulatory Affairs: Global Compliance and Strategic Readiness

MIKE KING, Senior Director, Product & Strategy, IQVIA
ALEX DENOON, Partner and Head of Life Sciences and Regulatory Team, Bristows LLP
CHRISTOPHER HART, Partner, Co-Chair, Privacy & Data Security Practice, Foley Hoag LLP

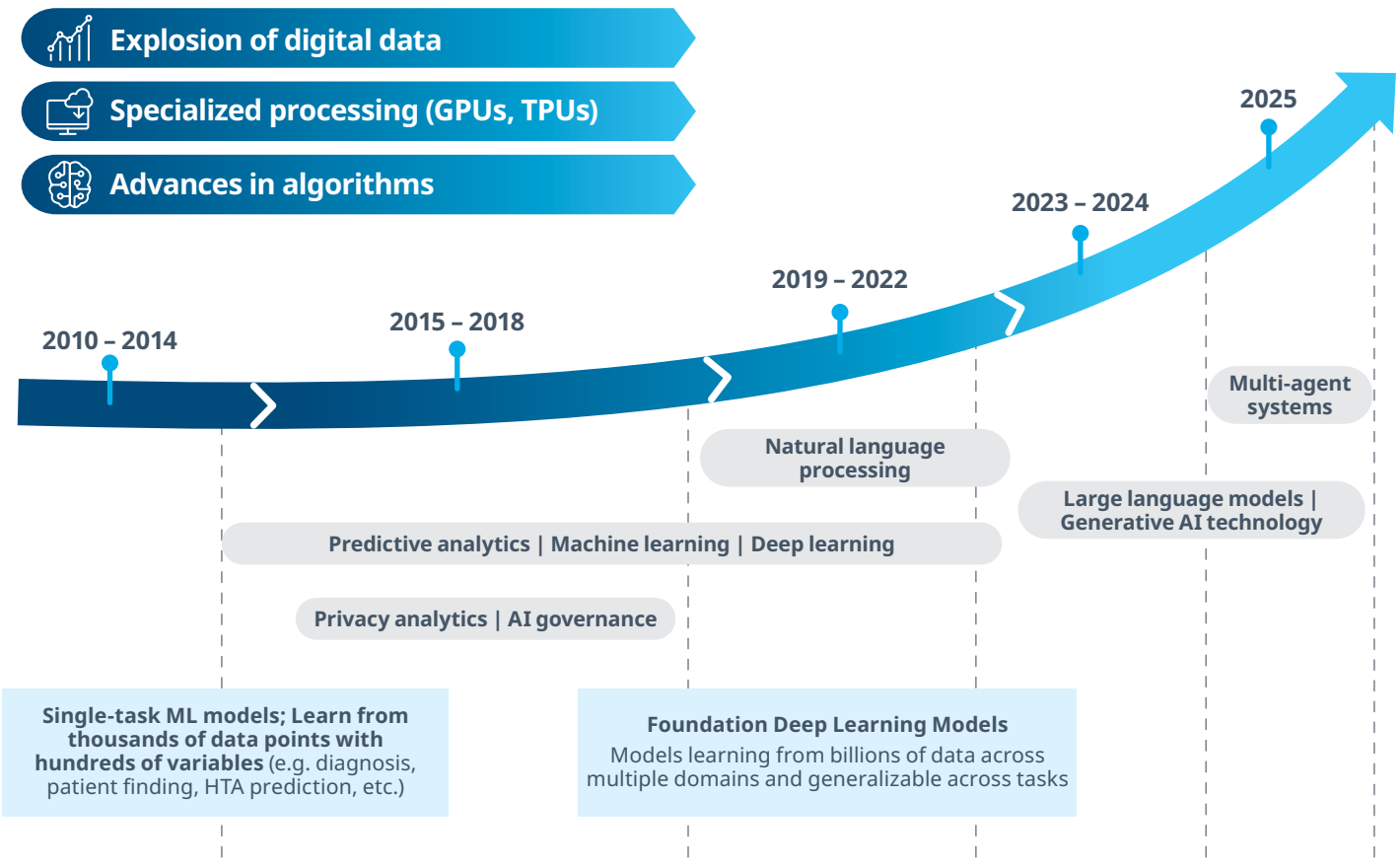
Table of contents

Introduction

Artificial intelligence (AI) has been evolving for nearly 70 years, from basic pattern recognition to advanced machine learning, language models, and agentic AI capable of autonomous decisions. Historically, in-depth knowledge of AI was largely constrained to engineering and computer science professionals; now, the general availability of touch-screen technology and the public's accessibility to high-computational-powered devices means that a broad range of individuals are sharing their views on how AI-enabled technology could support advancements in patient care. No longer an emerging technology, AI has become mainstream, capturing the hearts and minds of people across professions and industries.

Today, AI applications in life sciences span diagnostics, clinical decision support, medical imaging, digital therapeutics, drug discovery, manufacturing and production controls, shipping and logistics support, and business analytics (to name just a few). This white paper examines the use of AI in life sciences from a quality assurance and regulatory affairs (QA/RA) perspective, highlighting key takeaways from legal experts in the healthcare regulatory space and QA/RA specialists. The bottom line is that the use of AI as an enabler in healthcare should drive improved patient safety, product quality and commercial performance in the provision of safe and effective global product solutions.

Figure 1: Increased data availability and computing power have allowed foundation deep learning and LLMs to evolve in the AI space



The AI landscape in life sciences

AI is already widely used in areas like radiology and production control. Newer applications within the life sciences industry include:

- Driving insights into product performance through the mining of structured and unstructured data in sources such as government recall databases and adverse event reports, technical service records, and clinical content.
- Powerful deep analytics so the trends and signals can identify potential deviations in product and process performance and/or changes in product safety profiles that need urgent investigation before "small sparks become large wildfires."
- Creation of generative content for human review in core quality management system (QMS) and regulatory information management (RIM) processes including global regulatory submissions and product registration activities, adverse event reports and recall/field action notifications, product labeling/packaging/marketing literature, and CAPA/audit summaries as examples.

With all these applications, AI-enabled QMS and RIM activities have the potential to strengthen the global compliance activities of QA/RA professionals and provide them with more time dedicated to product quality, patient safety, regulator relationship and market access activities, thereby driving commercial performance alongside the provision of patient-centric solutions.

Alex Denoon: I only work in the life sciences sector, and everyone I work with is either currently deploying, about to deploy, or investigating where to best deploy AI, a lot of it generative... everyone is convinced of the productivity gains and healthcare benefits that can come from AI. Every single large client I have is already well and truly invested in this space. I don't think there is a single problem that is too complex, too trivial, too simple or too multifaceted that AI can't help. I would say that the particular difficulties relate to how you direct it, how you govern it, how you control it, and the guardrails you put around it.

Christopher Hart: It's important, when we're talking about AI, that we understand that it's a very capacious term. It encompasses a number of different kinds of technological tools. ... There's an enormous amount of interest in adoption, and it's driven by a number of different kinds of motivations. ... One of those

motivations is, of course, simply, how do you do your job more efficiently in order to drive the bottom line, in order to get the most out of a workforce? It's also, how do you do the job better? ... But I think the third is also just pure competition and understanding that if you don't adopt generative AI tools in some fashion in your work, you are going to be left out as a competitive player in the marketplace.

The rapid evolution of AI has the potential to enhance patient outcomes by improving clinical trials, medical diagnosis and treatment, self-management, and personalized care. While generative AI is being increasingly prioritized within the life sciences industry and is expected to drive substantial economic impact, organizations must be mindful that AI errors in healthcare can have significant, far-reaching consequences. Thus, it is crucial that AI-powered devices, products and solutions, along with their training data, are regulated and compliant to protect privacy, ensure suitability and maintain patient safety.

With the rise of generative AI and real-world use cases in diagnostics, monitoring, and treatment optimization, the life sciences industry — medical devices, in vitro diagnostics and pharmaceuticals — faces growing pressure to implement AI safely, ethically, and compliantly. This requires a robust understanding of approach to quality assurance (QA) and regulatory affairs (RA). Knowledge of the "vertical" regulations and standards that apply to medical devices, in vitro diagnostics, pharmaceuticals and biologics must be complemented with knowledge of the "horizontal" regulations that step broadly across industries. These horizontal regulations include data protection, environmental health and safety, and now AI.

AI can support quality assurance and regulatory affairs activities

When it comes to the activities of QA/RA, either in utilizing QMS and RIM solutions or in driving the product innovation pipeline and patient-focused therapies, AI-enabled solutions offer a significant area of opportunity and can drive a dual focus on patient safety and commercial performance.

As Figure 2 shows, AI can be used to support a variety of QA/RA processes, taking some of the pressure off QA/RA professionals through either accelerating process efficiency or improving the effectiveness and quality of performance. As with all adoption of AI within life sciences, these pragmatic AI solutions need to be robust and regulated and deployed in a way that recognizes the constraints of a highly controlled healthcare environment.

AI-enabled solutions offer a significant area of opportunity.

Figure 2: Pragmatic AI

Patient safety, product quality, market access

Data search and extraction

- Product design and development
- Global regulatory requirements
- Post-market surveillance

Content review

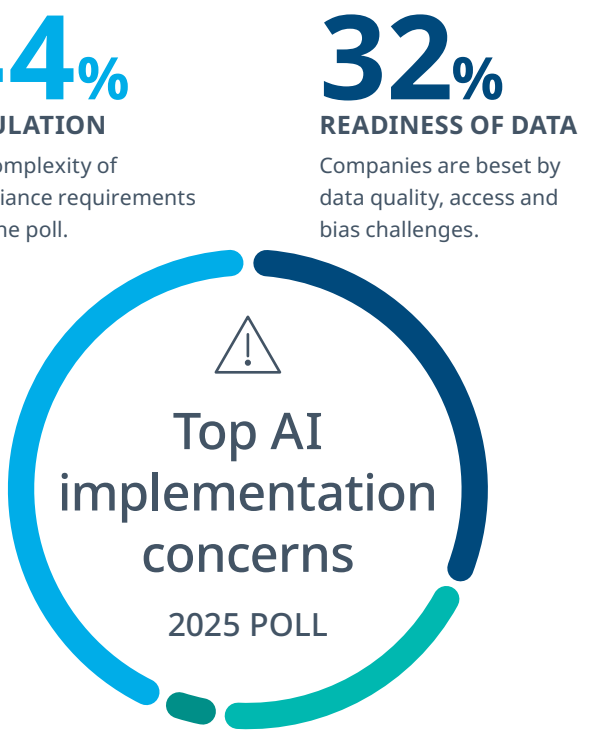
- Global regulatory approvals
- Electronic health records
- Market launch insights

Education and training

- Patients and clinicians
- Company employees

Why are some life sciences professionals reticent in fully embracing AI?

It has been estimated that generative AI could "unlock between $60 billion and $110 billion a year in economic value for the industry",[1] but only a small percentage (5%)[2] of organizations have realized generative AI benefits, and support is needed to shift from exploration to deploying sustainable solutions. A recent poll, conducted by IQVIA prior to our webinar, identified the below as the top concerns of healthcare companies when implementing AI in healthcare QA/RA:



1 Scaling gen AI in the life sciences industry, Chaitanya Adabala Viswa, Dandi Zhu, Delphine Zurkiya, and Joachim Bleys, January 10, 2025

2 Scaling gen AI in the life sciences industry, Chaitanya Adabala Viswa, Dandi Zhu, Delphine Zurkiya, and Joachim Bleys, January 10, 2025

Mike King: It's not surprising that regulator and quality teams lean into regulation first… if you take a customer-centric approach to applying AI to certain use cases, you have to start with the regulations.

Denoon: It doesn't surprise me that the only criteria here [in the poll] that could result in you going to jail was the highest priority. That's the way that gets most attention, and regulation is the only go-to-jail point. I agree hugely with that balance.

Hart: I'm going to echo what Alex and Mike have said. The only thing I would say is that, to the extent that we have a global audience, as opposed to a U.S. audience, if this were a U.S.-only audience, I might think about that regulation being a little bit lower, simply because of the U.S. federal government's decision to more or less keep a hands-off approach.

The poll's outcome is a shrewd acknowledgment that regulatory compliance is, as Denoon stated, the only potential "go-to-jail" moment, and thus the highest priority for risk-averse healthcare organizations. The complexity of navigating the "vertical" and "horizontal" regulations applicable to healthcare has been compounded by AI. However, the benefits of the deployment of focused AI solutions are significant.

Innovation of AI within life sciences technologies seems to be evolving at a higher rate than regulatory bodies can keep up with, but organizations, however excited by the possibilities of these innovations, must assess the risk-benefit of the use of AI technologies and understand the pitfalls as well as the positives that AI delivers. Company-specific, AI strategic plans should include data literacy and AI literacy components and build in regulatory surveillance activities to ensure an organization can readily adapt to new and emerging laws and meet emerging standards. Regulatory bodies are increasingly expecting organizations to anticipate and manage AI-specific risks, such as hallucinations and algorithmic bias. Connecting data, technology and expertise will help realize the full potential of AI in healthcare and life sciences safely and responsibly.

QA/RA teams can use existing skills to navigate the AI landscape

QA/RA professionals naturally gravitate to evaluating the risk-benefits of healthcare solutions and the potential failure modes of product and processes alike. In the era of enhanced focus on AI, core development principles familiar to a QA/RA professional can be drawn on to steer the deployment of AI-enabled solutions in a way that drives value to product and/or process quality, cost and/or compliance. The strategy to navigate complexity is to lead with the customer problem statement and solution outwards, choosing the right tool for the job.

A layered AI-implementation strategy is recommended:

- Define the **problem**.
- Understand applicable "vertical and horizontal" **regulations and standards**, accommodating for global variance.
- Assess **data readiness (congruence, volume, specificity, quality)**.
- Evaluate **organizational readiness**.
- Solution outwards with these variables in mind, considering the **cost-effectiveness of any AI solution**, choosing the right type of AI (if any) suitable for the original problem statement.
- Support with core quality methodology and continuous improvement approaches.

Targeted AI use cases need to support the deliverable of global, affordable patient solutions, adding value to cost, quality and time.

Key to this are:

Transparency **Governance** **Trustability**

Examples of use cases in which AI/NLP (natural language processing) can be applied to help improve patient outcomes are: **post-market surveillance**, to search structured and unstructured data at scale to identify potential adverse events and product quality issues; **content review**, where AI is used to efficiently review scientific papers, clinician notes and inpatient/outpatient notes to give product usage and patient outcome insights; and **communication insights**, where AI can track and monitor the impact of internal and external communications across a range of social media and electronic channels.

Key takeaways from QA/RA experts

IQVIA Technologies recently facilitated a panel discussion between experts in the regulatory landscape. Mike King, Alex Denoon, and Chris Hart highlight considerations for QA/RA professionals to help them ensure compliance, quality, and patient safety while navigating the challenges and opportunities of AI in healthcare:

- **Stay informed and adaptive:** The regulatory landscape for AI in healthcare is rapidly evolving and complex, with significant differences across regions (e.g., U.S., EU). QA/RA professionals must stay updated and be ready to adapt to new regulations and standards.
- **Transparency and governance:** Establish clear governance structures and ensure transparency in AI deployments. This includes documenting where and how AI is used and having accountable individuals or teams overseeing AI activities.
- **Bias mitigation:** Implement frameworks to identify, assess, and mitigate algorithmic bias. Regularly audit AI systems for fairness and accuracy, as bias can have significant regulatory and ethical implications.
- **Participate in standards development:** Where possible, actively engage in the development of industry standards and guidance for AI, or at least monitor and prepare to comply with emerging standards.
- **Assess appropriateness of AI:** Carefully evaluate whether AI is the right tool for each use case, considering data availability, regulatory requirements, and patient outcomes.
- **Documentation:** Maintain detailed documentation of the rationale behind AI deployments and decisions. This is crucial for regulatory compliance and for defending decisions if challenged.
- **Consult legal counsel:** Work closely with legal experts to ensure documentation and practices align with regulatory expectations and to manage potential legal risks.

QA/RA professionals must stay updated and be ready to adapt to new regulations and standards.

Denoon: I'd add, AI tools are the best at monitoring whether an AI tool is going awry. They're much better than humans at monitoring them. All of my very large clients use multiple different tools all day, every day, to cross-interrogate the tools they're using to triangulate back.

King: The outcomes are around patients, and patient outcomes. AI is one of many tools, albeit a brilliant one, but we always need to make sure that we're focused on the true deliverable, which is safe and effective, global patient care.

Hart: One of the things that's very important in AI frameworks tends to be the protection against algorithmic bias… Figuring out how to control for bias, both in the training inputs as well as in the use of outputs, is extremely important. And that has a governance consequence, which is that you have to constantly assess these tools, to constantly assess what outputs are coming from it, and how they're being used, and in what ways they may create some sort of prejudicial bias.

AI tools are the best at monitoring whether an AI tool is going awry. They're much better than humans at monitoring them.

Why this matters now

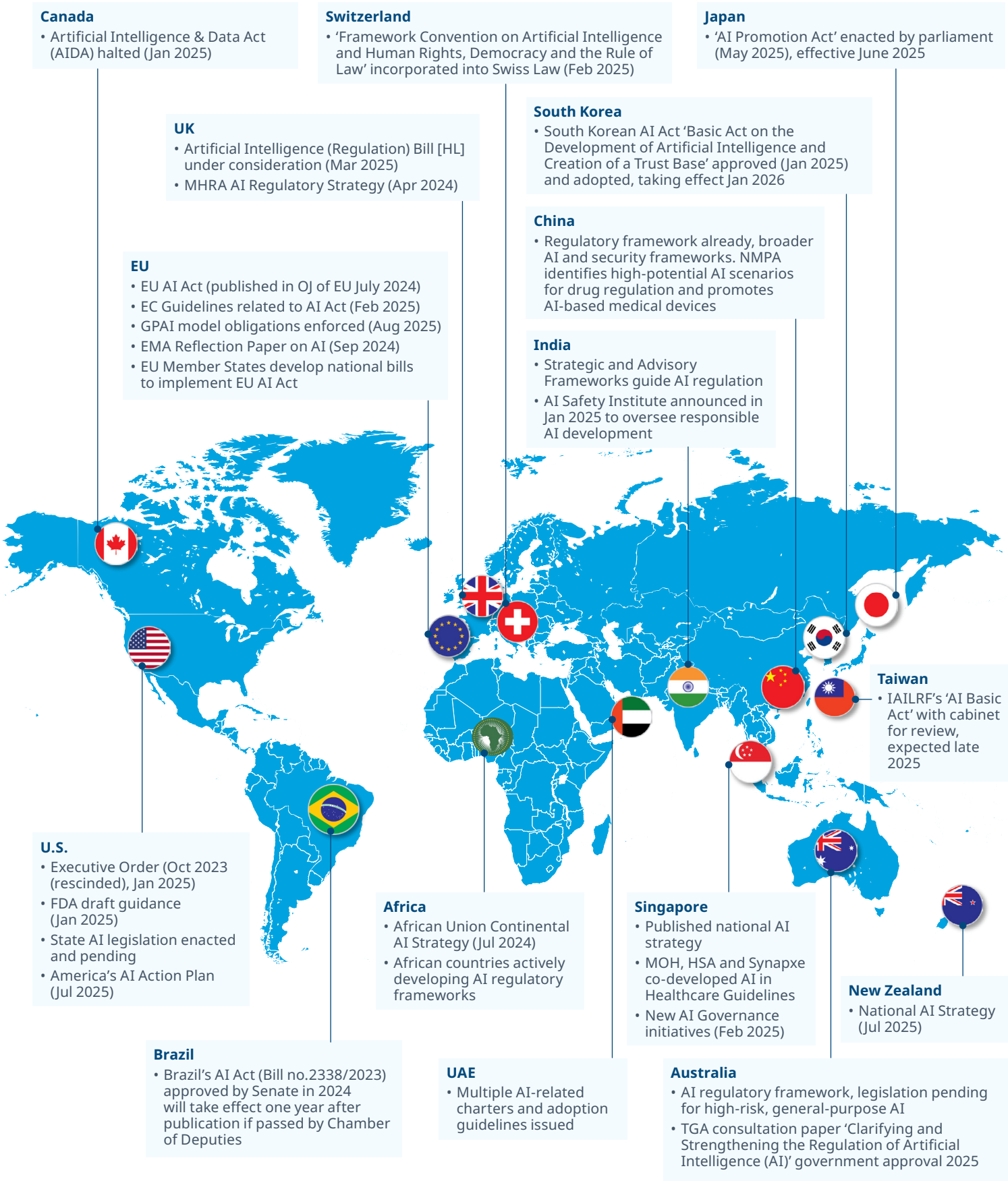
Data quality, structure and congruence remain major hurdles; effective AI solutions require well-prepared and curated data and an organization with a level of data literacy and AI literacy to drive sustained, long-term benefits from AI-enabled activities. AI is already making processes more efficient and identifying patterns in data more quickly than a human eye ever could. But there are risks associated with generative AI, such as hallucinations, bias and outdated information, making human oversight essential. Regulatory compliance, transparency, governance, and trust are critical to protect patient safety. Different products in different markets have different regulations, with new guidance emerging continually. It is critical that any generative AI models can account for such changes in landscape and provide outputs that are both current and without hallucination.

In the last three years, significant AI regulatory developments have occurred globally, most notably with the EU AI Act[3] coming into force in August 2024 and the UK publishing a pro-innovation white paper on AI regulation in March 2023[4], and hosting the first AI Safety Summit in November 2023.

For organizations looking to market products in global countries, when it comes to AI, similar principles to those used for global product registration activity apply. It is necessary to ensure that AI requirements in target markets are fully understood as they could directly impact product design. Additionally, local variances in AI regulations need consideration for quality management and regulatory systems.

3 The EU Artificial Intelligence Act, Up-to-date developments and analyses of the EU AI Act, Future of Life Institute (FLI)
4 A pro-innovation approach to AI regulation: government response, Department for Science, Innovation & Technology, updated 2024

Figure 3: The global AI regulatory landscape continues to evolve



Not an exhaustive list. Subject to change.

Hart: The U.S., I think famously, has layers of regulation, both at the federal and state level. … I would say there's been a real shift, at least at a federal level, from a focus on safety to a focus on innovation and competitiveness… In the QA/RA space, there is the development of products that make certain kinds of guarantees or representations around what they can accomplish — what is going to be used, how safe and secure that data might be, how accurate it might be. Those are still subject to consumer protection laws so governed by, for example, federal agencies that can enforce against violations of those kinds of representation. They're also regulated at the state level, and I think that's really where there's a more interesting question: what does state regulation look like? States have made various attempts to regulate AI across industries, be it through measures around transparency or measures around governance or registration or consumer rights or whatever the case may be… it's a work in progress.

Denoon: Europe loves to regulate. So, we have these astonishingly broad regulatory frameworks like GDPR and the EU AI Act…. if you're compliant with them, you get a huge chunk of the world because so many countries piggyback off European frameworks. So, the good news, once you've got your brain wrapped around the requirements of data protection, AI Act and, to a lesser extent, MDR, IVDR, you really do have a very strong compliant tool that will be readily usable in other jurisdictions. But as Mike said, there are lots of things coming from surprising angles on a very regular basis and, as Chris said, some of those are going to be state based. So there is a lot to keep on top of… to a large extent, companies will be given quite a lot of scope to find their own balance and their own risk assessment. Unfortunately, that's never going to give them an absolutely perfect framework. But the good news is, the European frameworks do actually deliver a degree of certainty.

King: Now programmers, or those that can use AI tools, are at the forefront of a whole host of industries. Public awareness of those types of tools is significant… there is an increased public expectation of having good, safe, effective healthcare solutions, plus an accessibility and awareness of how certain AI solutions could help drive cost-effective and quicker access to healthcare have come together in this current era. Organizations need to be cognizant of the fact that healthcare is a regulated industry, and data governance within AI-enabled solutioning must be delivered in the right way to be on the right side of global governance and drive accelerated provision of safe and effective patient solutions.

There's been a real shift, at least at a federal level, from a focus on safety to a focus on innovation and competitiveness.

Conclusion

AI in life sciences is transitioning from broad excitement to targeted, practical applications, with established use in some domains and emerging opportunities in others. The focus is shifting toward pragmatic, customer-centric use cases that deliver measurable value in quality, cost, and timeliness. The landscape is shaped by both technological advances and the need for careful governance to ensure safety and effectiveness. The evolution and integration of AI within life sciences technologies has contributed to the complexity of existing and emerging regulations and standards, but AI itself has the potential to help organizations navigate this complexity.

AI promises streamlined compliance and enhances decision-making in safety and regulatory processes, but balancing AI's innovative potential with the need for regulatory-grade accuracy and trustworthiness is crucial. Ultimately, the critical focal point for healthcare must, and always will be, the patient and clinical outcomes. This is no different for AI-enabled activities that are driven by QA/RA professionals across QMS and RIM activities.

Focus clearly on one or two key use cases that offer the most value for your business.

Final thoughts from experts in the life sciences regulatory space:

Denoon: My clients who get the biggest bang for their buck already are the ones who in the QA/RA space are using it [AI] to help them with advertising and claims management. You generate a lot of benefits and a lot of productivity very quickly.

King: Focus clearly on one or two key use cases that offer the most value for your business and clearly define the problem statement at hand. If you capture those two things together, as you solution up, you end up in a good place… Pick one or two good things, focus, deliver, drive value, communicate value, and offer the benefits. Reinvest back into some new projects.

Hart: I think the regulatory environment is going to shift in some unexpected ways, both in terms of which jurisdictions are going to be particularly aggressive, and other jurisdictions that might want to be innovative. And so, I think not assuming that tomorrow is going to look like today is probably a good idea and trying to incorporate the best practices that we've discussed, I think would be the best way forward.

About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of clinical research services, commercial insights and healthcare intelligence to the life sciences and healthcare industries. IQVIA's portfolio of solutions are powered by IQVIA Connected Intelligence™ to deliver actionable insights and accelerate innovations. With approximately 88,000 employees in over 100 countries, IQVIA is dedicated to accelerating the development and commercialization of innovative medical treatments to help improve patient outcomes and population health worldwide. Learn more at www.iqvia.com.

About the authors

MIKE KING
Senior Director,
Product & Strategy,
IQVIA

With over 20 years of experience leading global teams in regulatory affairs and quality assurance, Mike King, as Senior Director of Product and Strategy at IQVIA, ensures healthcare solutions meet complex global regulations and oversees platforms like SmartSolve® eQMS and RIM Smart to streamline quality and regulatory compliance processes.

CHRISTOPHER HART
Partner, Co-Chair,
Privacy & Data Security Practice,
Foley Hoag LLP

Chris Hart is a litigation partner and co-chair of the Privacy and Data Security group at Foley Hoag LLP. With nearly two decades of civil litigation and human rights experience, he guides clients through complex data privacy and cybersecurity issues, including compliance, incident response, government investigations, and litigation.

ALEX DENOON
Partner and Head of Life Sciences and Regulatory Team,
Bristows LLP

Alex Denoon heads the life sciences regulatory team at Bristows. He has more than 25 years' experience advising clients in the sector. In addition to his LLB, Alex has a BSc in Human Genetics. Alex spent more than five years in-house, including as GC and Company Secretary of Biotech Australia. He works with clients to devise and implement regulatory strategies throughout the product life cycle of pharmaceuticals and medical devices and advises clients in relation to more challenging issues including: genomics, cell therapies, tissue and cells requirements, borderline products, combination products, 3D printing, healthcare apps and remote diagnostics, and has been involved in the development of a number of regulatory frameworks and guidelines.

CONTACT US

iqvia.com/smartsolve

IQVIA TECHNOLOGIES