

White Paper

# Accelerate Global Market Access with Confidence

*How AI-enabled regulatory information management (RIM) transforms compliance*

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# Introduction

The changing nature of global regulation and compliance rewards agile minds and forward-thinking organizations. At the same time, it is testing the patience of the very best practitioners in the field. Increased complexity, growing regional variations, constant updates, and ongoing concerns about data quality combine to create barriers and challenges that must be overcome.

At its heart, this white paper explores the present and future role of regulatory information management (RIM) and the value of professional, global regulatory expertise. It evaluates the merits of digital RIM solutions but also lays out why a sizeable number of organizations remain resistant to change. This white paper seeks to understand that resistance, present the benefits of digital RIM solutions, explore the role of artificial intelligence (AI), and offer advice and best-practice experience about adoption.

The insights and expertise shared on the following pages are drawn from an IQVIA LinkedIn Live webinar, Accelerate Global Market Access with Confidence: How AI-Enabled Regulatory Information Management (RIM) Transforms Compliance, which took place in February 2026. The expertise comes from three thought leaders: Asheeta Anand, Director, Regulatory Affairs & Quality Assurance, Dentsply Sirona; Jeremy Yung, Regulatory Affairs Director, Cynosure Lutronic; and Mike King, Senior Director, Product & Strategy, IQVIA. Their opinions and their analysis of market, customer, and technology trends are reflected here.

*The changing nature of global regulation and compliance rewards agile minds and forward-thinking organizations.*

## Seven key takeaways

- 1 Spreadsheets are a symbol of cultural inertia.** A sizeable minority of organizations continues to use spreadsheets, shared drives and other piecemeal tools to manage regulatory information. This is indicative of a cultural, as well as technological, challenge.
- 2 Coping without a digital RIM solution is like operating without ERP.** And that's the situation many global regulatory teams find themselves in today.
- 3 Rethink communications to secure leadership buy-in.** Talk the language of the business, focus on outcomes and benefits, and reframe the role of the global regulatory team, not as a cost center but as a facilitator of competitive advantage and market access.
- 4 Don't forget to secure team buy-in, too.** It's not just leadership that needs to be persuaded; it's your regulatory colleagues, too. To challenge cultural inertia (see point 1, above), you must make the case for change and champion the transition to the future state.
- 5 Approach AI with cautious optimism.** RIM-focused use cases abound but don't forget the human in the loop and the ability to explain AI decision making.
- 6 Avoid the perils of siloed systems and embrace integration.** Assimilating RIM, quality management system (QMS), and enterprise resource planning (ERP) data speeds regulatory submissions, minimizes ongoing maintenance, and reduces the risk of error.
- 7 Remember, technology is an enabler.** Ultimately, it's the application of technology, not the technology itself, which really matters. It's there to help improve global healthcare outcomes and should be judged on those terms.

# Global trends. Regional impact

## Complexity, volume, and cost

Take today's economic headwinds and constraints and add the potential impact of AI as well as industry-specific changes to global regulatory regimes designed to demonstrate the safety and efficacy of healthcare products. The result? An industry dealing with levels of complexity never encountered before. The speed of change is unprecedented, too, with the scale of the challenge affecting many global countries.

While the scale is global, for many organizations the specifics are regional, sometimes on a country-by-country basis. The ability to develop strategies and tactics to meet these trends, barriers, and impacts is what will distinguish the successful companies from the rest.

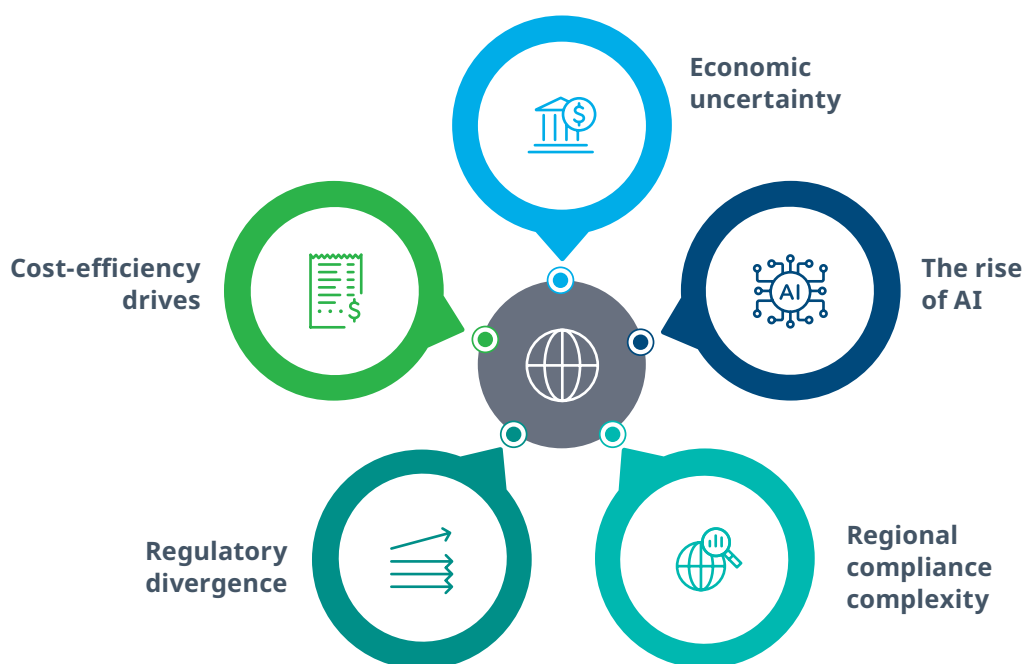
**Asheeta Anand:** There is a huge increase in compliance requirements within the regions, especially in APAC [Asia Pacific] and EMEA [Europe, Middle East, and Africa], which might explain why everybody's looking at AI. Facing these complex regulatory requirements necessitates a good balance of speed and resilience.

If we do not have a good understanding of regional regulatory requirements, then it will affect market access timelines. For example, in India it takes 9 to 12 months to launch a product; in China it takes up to 24 months; and in Russia up to 24 months too, assuming all goes according to a realistic plan.

**Mike King:** What are global regulatory teams looking to achieve? To optimize their go-to-market processes and do so while navigating this complex environment in a way that drives cost-effective compliance. This ultimately allows companies to bring critical healthcare solutions to market with predictable timelines.

**Jeremy Yung:** It's getting increasingly more challenging to stay abreast of regional regulatory compliance. We are seeing more regulations, and more complexity as regulators both mature and tackle new technologies and challenges. At the same time, global organizations, especially with the current economic situation unfolding around the world, are being asked to do more with less. So not only do you have to keep up to date with these regulations but you have to manage projects and compliance initiatives with fewer regulatory professionals.

Figure 1: Global trends and barriers



# The role and benefits of RIM

## And introducing IQVIA SmartSolve® RIM

RIM, in all its forms, provides a structured system for collecting, managing, and maintaining compliance-related intelligence and documentation. It does so across the lifecycle of a healthcare product. Data can be stored and shared to complete several essential tasks including submissions, registration tracking and health authority interactions. It automates workflows, accelerates time-to-market, reduces non-compliance risks, and helps ensure adherence to global regulations and standards.

The features and benefits of digital RIM systems include:

<b>GREATER EFFICIENCY</b>	RIM simplifies data collection and management across the product lifecycle, automates time-burdensome tasks, and avoids unnecessary duplications of effort.
<b>RISK REDUCTION</b>	RIM guarantees a single source of accurate and audit-ready data, which helps reduce errors and improve timely, global regulatory compliance.
<b>INCREASED VISIBILITY</b>	RIM ensures that all data on the status of a product is accessible in one place and accessible to all those individuals, across business functions and global regions, who need access.
<b>CENTRALIZED REGULATORY MONITORING</b>	RIM offers a one-stop shop for global regulatory intelligence and monitoring changes to enable continuous compliance and sustained market access.

*“A digital RIM solution is about having a system that’s been validated by regulatory professionals — one that can save us a lot of time.”*

— Jeremy Yung

**Anand:** A lot of companies have multiple data management platforms. To put all of that data relevant to global product registrations into one system and then leverage your data to get the approval outputs you need in less time — that’s the advantage that RIM provides. This is particularly the case in smaller markets. If you look at APAC, we’ve got markets like Vietnam that are very tiny on the map but have high complexity when it comes to registrations. With RIM, you can optimize the information you have and maximize the output of local regulatory professionals.

**Yung:** It’s about doing more with less. A digital RIM solution is about having a system that’s been validated by regulatory professionals — one that can save us a lot of time, rather than creating these systems from scratch.

**King:** Let’s play “Imagine if.” Most companies have been using an ERP solution for twenty, thirty, or forty years. Imagine if that was taken away tomorrow. Imagine global ordering, shipping, and logistics activities having to be run through SharePoint sites, emails, and Excel spreadsheets. That would be disastrously slow and risky, particularly when you’re looking at inventory mapping, logistics, customs clearance, and all the things required to take an order from a customer and execute delivery to that very same customer. This may sound like a crazy scenario. But if you look at the absence of a digital system and the impact that has on professional activity, that is what most of our global regulatory teams are coping with today — spreadsheets, SharePoint sites, and emails. And when you look at it through that lens, you can begin to see the power of a digital RIM solution. Empowering teams with a digital solution helps them have more time to focus on truly strategic, innovative market access activities — and ultimately that’s what we want to be doing more of as regulatory professionals as that is how we can make a difference in patient outcomes.

## IQVIA SmartSolve® RIM: Streamline global compliance and accelerate market access

SmartSolve RIM, built on the trusted SmartSolve® platform, is an AI-enabled, cloud-based solution for MedTech, IVD, and pharmaceutical organizations. It unifies regulatory and quality workflows, automates compliance, and delivers real-time insights, so your team can move faster and with confidence. From creating regulatory content to managing global product registrations and lifecycle updates, SmartSolve RIM simplifies complexity and speeds approvals worldwide.

Figure 2: End-to-end regulatory management



Submission and publishing management



Registration management



Health authority interactions



Document management



Change management and event management

*SmartSolve RIM unifies regulatory and quality workflows, automates compliance, and delivers real-time insights, so your team can move faster and with confidence.*

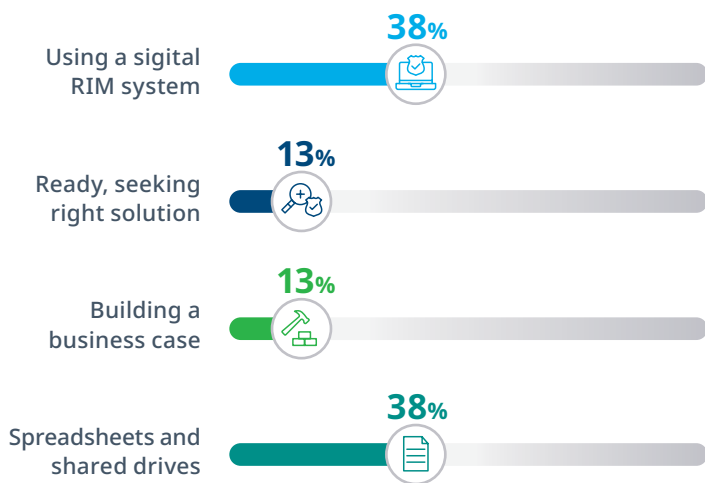


# Resistance to change

## And making the case for digital

The embrace of digital systems is happening at a varied pace, as our pre-webinar poll demonstrated. Regulatory professionals were asked to describe their organization's approach to digital RIM systems. As many respondents (38%) said they were continuing to use spreadsheets, shared drives and other piecemeal tools to manage regulatory information as said they were currently using a digital RIM system. Those not at either extreme are either building a business case for digital RIM adoption (13%), or are ready to adopt and were currently assessing the right solution.

**Figure 3:** What best describes your organization's approach to digital RIM systems?



**Yung:** I'm not surprised at all by the results, especially in the use of spreadsheets and shared drives. At several points in my career, I've been guilty of doing that, too. But spreadsheets and shared drives only evolve to a certain point of use. After that, it gets a little bit messy. Spreadsheets were what was most readily available and what we could slap together as a team and agree on to drive a certain level of optimization. You could describe it as the minimum viable product (MVP) for global registration activities.

*"If your company's resource restraints are considerable, then you have to implement a system that's going to support you and make your work much, much faster whilst retaining compliance with global regulations."*

— Asheeta Anand

**Anand:** Lots of companies are still bound by spreadsheets — the things that you can save on your desktop and in the shared drive — that can be accessed and made read-only. So there's a level of control in that approach for the regulatory teams. They're the ones we need to convince that RIM systems do work. Ultimately, everybody must get on the bandwagon. Realistically, how long can we use trackers and spreadsheets in an environment of ever-increasing complexity? Eventually, we have to get onto a single system if we want to be speedy, to get to the market fast. And if your company's resource restraints are considerable, then you have to implement a system that's going to support you and make your work much, much faster whilst retaining compliance with global regulations.

Whether all of those on the path to digital RIM complete that journey is a debatable point. What is clear, however, is that a sizeable minority of organizations — over a third in total — are resistant to change. Exploring why this is the case is instructive.

Among the reasons cited are cultural inertia, a misreading of cost-benefit analysis, and a failure to properly communicate the business value of digital systems such as RIM. A return on investment argument has always been tough to make because the regulatory function is typically characterized as a cost center. On cultural inertia, most individuals hold on to the security blanket of what works. This feeds a reluctance to advocate for change.

**King:** One inhibitor to adoption is the regulatory professionals themselves. When we sit in organizations, we can often see the need to harmonize and the need to digitize. But quite often, we want everyone to harmonize around the way we do things. That natural reluctance to change — particularly within a cohort that is naturally risk averse — can sometimes inhibit the initial uptake of a digital RIM solution.

**Yung:** From my experience, the regulatory function has always been seen as a cost center. Regulatory approval is just seen as an expense on the pathway to making money. And the argument goes like this: “Why add to that cost with another digital system when regulatory teams can make do with spreadsheets?”

**Anand:** The hesitation that comes from leadership, in my opinion, is the initial cost investment. Anytime you need to implement a RIM system, you need resources. You need the resources to get data into the system if it’s going to give you what you need. It’s a question of cost. And teams leading the push for investment into digital RIM solutions need to show the positive value associated with that cost.

## Making the case for RIM

If those are the reasons for resistance, how do forward-thinking regulatory practitioners make the case for change, the case for RIM adoption? First and foremost, by making the business case. That means expounding the efficiency saving, process improvement, and risk mitigation merits of a digital RIM solution. It means talking the language of the business and explaining the benefits in terminology that resonates with leadership.

**Yung:** RIM is about efficiency for the organization and the regulatory team, too. Make the business case strong by providing examples. Explain to the leadership team that they can go straight into a RIM system summary and see exactly where their products are registered. They can discover the estimated approval time in country X, for example, of a registration that is in progress. A digital RIM solution is going to give them better forecasting capabilities, better information sharing, and better global marketing plans associated with product launches.

For the regulatory teams, it means less trawling through multiple spreadsheets for data and status updates; fewer emails and PowerPoint updates to stakeholders and more regulatory work done.





**Anand:** In the end, the regulatory team’s output is much higher; your company’s return on investment is much higher. And long term, even with less investment in additional regulatory headcount, you can get more work done through empowering the teams that you already have. In addition, if you’ve got multiple ERP systems and you’ve got multiple data management systems, you can integrate them with a RIM solution and reduce the time needed to chase data and reduce the risks from manually consolidating different data sources.

**King:** Regulatory teams are facing a challenge of communicating what is quite a complex environment, in a way that is simple and well understood by leadership. As we begin to communicate the value

of what global regulatory teams can do, and as we focus on patient outcomes, leadership teams will realize that investment in digitized RIM — or indeed digitized QMS too — directly drives improved commercialization, improved innovation, and improved patient outcomes.

The art of communicating means speaking in their language, the language of the leadership team. We have a lot of technical terms, nuances, standards, and regulations that interplay. Instead of communicating with a lot of detailed technical jargon, we should be able to cut through that and convey a quite simple message: “If we invest X, the benefits are Y, the patient outcomes will be Z, and — from a market perspective — it will give us A, B, and C.”

## The peril of silos

In making the case for digitization, global regulatory teams should be prepared to alert senior leadership to the dangers of siloed systems and data. The benefits of integration should be made, and repeated often to ensure uptake of understanding.

An organization might, for example, deploy separate RIM, QMS, and ERP platforms. Not only will connectivity between these platforms allow companies to access related data and documents needed for a global registration or a regulatory submission, but it will speed up processes that would otherwise prove extremely time-consuming and bureaucratic in nature.

Moreover, integration reduces ongoing maintenance and the risk of error. By having a single data source — and by extension, a single source of the truth — rogue intelligence can be eliminated. All the advantages of integration, in turn, expose the disadvantages of fragmentation — and, ultimately, all play to efficiency and cost effectiveness.

**Anand:** Any system within a company — be it a QMS, ERP or RIM system — has to talk to the others to ensure that what you're seeking to get approvals for is communicated to all the different parties that play a part in bringing products to market. Your supply chain has to be aligned, your labelling has to be aligned, and your market-level requirements have to be implemented before that product is released to a particular market. If the RIM system and QMS are siloed, we're reliant on human power to then manually check and correct. In doing this, you are defeating the purpose of implementing RIM.

**Yung:** We do a lot of approvals in China and Japan, for example. Large markets like these have their own unique regulatory requirements. When it comes to the approval of Chinese licenses, it's getting to the point where one size doesn't fit all. A U.S. device can't just go straight into China without a lot of tweaking to that device within the QMS itself. So, if the RIM system doesn't communicate

with the QMS, you end up bringing non-compliant products into the country. They might be missing a Chinese label or an Instruction for Use (IFU) or the Chinese license number on the aforementioned Chinese label, for example.

**King:** The more fragmented your QMS, ERP, and RIM environments, the more points of connectivity there are, meaning the more the risk of error and the more maintenance required. And that, inevitably, pulls through to cost. What we're looking to do in industry is to use a digital RIM solution to drive cost-effective compliance. So the more fragmented your technological ecosystem, the higher the risk and, potentially, the higher the cost to configure that solution. Ultimately, controlled connectivity reduces risk, reduces complexity, and helps smooth and accelerate how products are brought to global markets to drive improvements in patient access to innovative healthcare solutions.





## AI and the future of RIM

### Human intervention is still required

Optimism tempered with caution. That neatly captures the expert view of AI as applied to regulatory information management. The benefits — from process effectiveness to optimized resource utilization — are manifest, as are the regulator-specific applications such as change control assessments and the compilation of regulatory commissions.

If the benefits are clear to see, the experts are equally clear-eyed about the potential risks — and for regulatory professionals, awareness of the regulatory threat is second nature. The overarching lesson is two-fold. First, AI execution must be accompanied by human supervision. Second, AI decisions must be explainable. Or as Mike King describes best practice: “AI empowered rather than human replaced.”

**Anand:** AI is a great tool, but you have to use it correctly, keeping in mind the compliance-related issues around AI. If you use the tool to enhance the work that you do then it will work perfectly fine, whether that’s AI-

implemented data management, the preparation of market-level dossiers, or change control assessments. But this does not replace a human being because the person that I have in Korea is much more knowledgeable about Korean requirements than an AI. Ultimately, it’s these local requirements that ensure the human remains a niche of expertise.

**King:** There are clear benefits to using AI in a controlled way to drive operational efficiency, process effectiveness, resource utilization, and compliance. And there are some key places where you can apply AI solutions: the compilation of regulatory submissions; the mining of precedent questions from authorities so you’re consistent in your responses; and an ability to review and curate information that has a higher probability of passing a review based on historic context.

**Yung:** As a medical device company, it’s essential to validate AI within your own field of expertise. We have to make sure that what AI has given us as an output is correct. As a regulatory professional, you need to validate AI for every output. If not, you risk a mistake and the consequences of that mistake will fall into your lap.

**Anand:** AI can be applied to the areas of data management, change controls, and submissions. For example, if I'm making a submission in the Middle East, I should not have to replicate that submission individually ten times over. AI can do that for me, and all I have to do is review it and then submit it. That can make life much easier and much faster. And speed is one of the things that top management looks for when we are carrying out registrations in local markets.

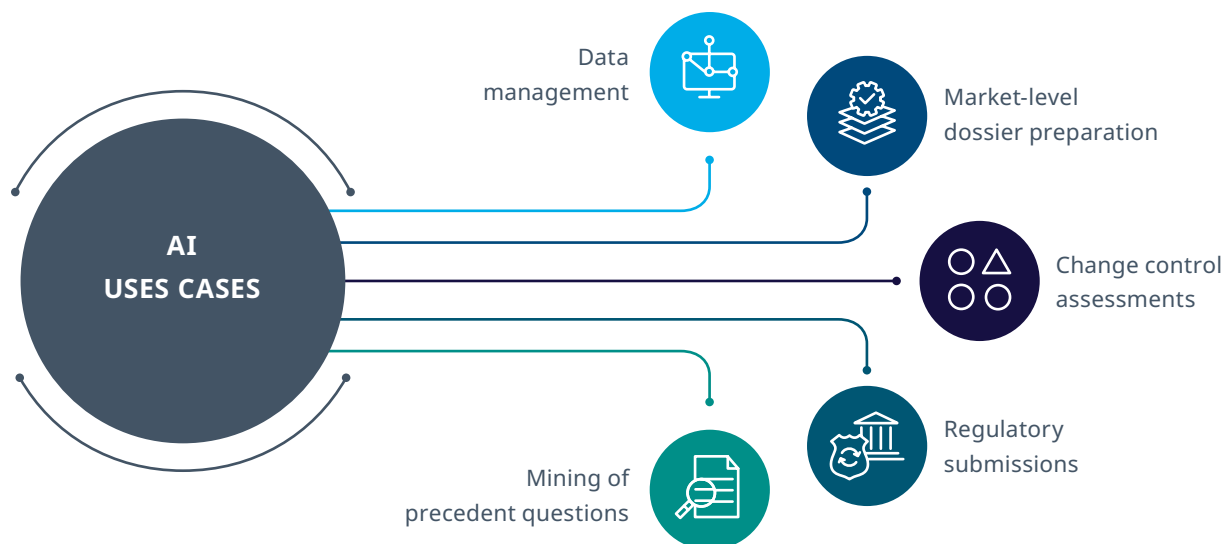
**King:** The key thing that we need to be mindful of is regulation. Yes, AI is a wonderful thing but, ultimately, the deliverable in healthcare must be safe and effective patient solutions. That means having a human-in-the-loop and being able to explain how decisions are made. A human-in-the-loop who can provide the clinical context and the professional regulatory judgement — applied to specific products, countries, and regulators — is critical. What AI can do is accelerate how you can get there, to improve the quality of what you're submitting, and to give insights into things that the human eye cannot see. That's why I would advocate for AI empowered rather than human replaced. The AI technology itself is not the end deliverable but rather an enabler to the provision of safe and effective patient solutions in global markets.



*“What AI can do is accelerate how you can get there, to improve the quality of what you’re submitting, and to give insights into things that the human eye cannot see.”*

— Mike King

**Figure 4: AI uses cases**



## Conclusion

Digital RIM solutions are a means to an end. The end is patient outcome, the ultimate barometer of how effective an organization's systems and processes are. Technology, when implemented effectively, is the enabler. And when implemented effectively, it drives efficiencies, reduces bureaucratic burden, and helps eliminate errors. It can accelerate global market access and, potentially, transform compliance.

As explored over the previous pages, some organizations remain resistant to the possibilities of digital RIM. This is as much a people issue as it is a technology or process issue.

By contrast, the experts featured here make a convincing case for adoption.

*Technology, when implemented effectively, is the enabler. And when implemented effectively, it drives efficiencies, reduces bureaucratic burden, and helps eliminate errors. It can accelerate global market access and, potentially, transform compliance.*

## Final thoughts from our RIM experts

**Anand:** Implementing a RIM system is one of the best investments that a company can make, especially from a regulatory perspective, because it makes life much, much easier. But there are a couple of things worth considering to improve implementation. First, you need alignment. You have to have the buy-in from your top management. And you have to have buy-in from your regulatory teams, your data management teams, and from IT as well. Second, you need to focus on the quality of your data. Make sure it's clean before you transfer it into RIM.

**Yung:** Make sure you also get buy-in from your own teams. Some may have been at the company for decades, and they're very happy with their spreadsheets. They are stakeholders, too, but by demonstrating the amazing potential of RIM, you will persuade them of the benefits. When you make the argument, usually people come on board and they get it very quickly.

**King:** Technology is great, but we're in the business of improving healthcare outcomes. So that means making sure that you have the right system in place — with the right support, and the right configurability — as well as the ability to curate data and documents in a way that works globally. Remember, technology is the enabler. So always have at the heart of what you're doing knowledge of your true vision. And that's providing global access to safe and effective patient solutions.





## 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 91,000 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](http://www.iqvia.com)

### About SmartSolve®

SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps life sciences organizations streamline and automate global quality management and regulatory compliance. [SmartSolve® eQMS](#) centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while [SmartSolve® RIM](#) manages regulatory submissions, product registrations, and health authority interactions. Built on industry best practices, SmartSolve connects teams, data, and workflows in a single platform to drive an optimized focus on patient safety, product quality and commercial performance.

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