FROST & SULLIVAN

2024 CUSTOMER VALUE LEADER

IN THE GLOBAL AI
REGULATORY AND
QUALITY SOLUTIONS
SPACE FOR HEALTHCARE
INDUSTRY

FROST & SULLIVAN

2024

PRACTICES



Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. IQVIA Identified as excels in many of the criteria in the artificial intelligence regulatory and quality solutions space.

AWARD CRITERIA			
Business Impact	Customer Impact		
Financial Performance	Price/Performance Value		
Customer Acquisition	Customer Purchase Experience		
Operational Efficiency	Customer Ownership Experience		
Growth Potential	Customer Service Experience		
Human Capital	Brand Equity		

Price/Performance Value

The business environment for healthcare organizations is more challenging than ever. Increasing complexity due to global regulations, financial performance that requires optimized resources, and complex healthcare solutions are driving the demand for artificial intelligence (AI). Globally, the regulatory and standards complexities continue to evolve. While there is a certain level of harmonization, countries maintain autonomy, leading to challenges such as custom inspections, country-specific quality standards, and considerations regarding registration and post-market operations.

Financially, organizations must remain profitable, whether they are small companies aiming to generate cash flow and build a pipeline to become acquisition targets or stock-listed companies looking to enhance shareholder performance. Quality assurance and regulatory affairs (QARA) professionals are tasked with managing this complex environment within the bounds of financial caution. Moreover, healthcare solutions are becoming increasingly intricate. For example, in the medical device sector, expertise is required both within companies and at the regulatory level, leading to more complex discussions. Al solutions in healthcare must consider this highly regulated industry environment.

Amid this scenario, IQVIA's combination of consulting, outsourcing, and technology solutions is transforming healthcare. To put things in perspective, specific features or industry-leading capabilities that highlight the company's value compared to competing solutions include IQVIA's comprehensive cloud solution portfolio, management and implementation consulting, business and IT managed services, and tech-enabled services. IQVIA's differentiated strategy is the combination of intelligence-driven

simplification, automation, and integration that leads to operational transformation. Therefore, the company's performance value lies not only in its enterprise quality management system (eQMS), SmartSolve, but also in its ability to integrate intelligence from various sources into regulatory submissions. The company uses AI embedded in IQVIA Vigilance Detect, which employs AI, natural language processing (NLP), and custom sentiment ontologies to uncover adverse events and product quality complaints across large and diverse datasets. Additionally, AI is embedded in IQVIA eQMS and in IQVIA RIMS, a fully integrated, cloud-based, end-to-end regulatory information management system. Together, these systems and their embedded AI contribute to fostering a single source of truth. This approach facilitates transparency and collaboration across functions, improves right-first-time outcomes—whether for product registration, audit responses, or safety events—and enhances commercial performance. By increasing the probability of right-first-time activity and mining precedent information to support that endeavor, IQVIA helps QARA professionals to achieve more with less, driving efficiency and effectiveness in compliance activities, all while optimizing speed and accuracy. One key aspect of IQVIA is its commitment to deploying quality management with a commercial focus, emphasizing both patient safety and commercial performance. IQVIA's AI can drive optimizations, insights, and efficiencies, allowing QARA professionals to improve patient safety and product quality within the bounds of financial prudence. Ultimately, IQVIA enables commercial performance through improved operational efficiencies and effective resource utilization.

Beschreibung wie gemeldet *

During an in-clinic interrogation, an episode of over-sensed noise was observed. Technical services were contacted and confirmed that poor telemetry might be the cause. The patient was scheduled for a follow-up visit the next day, but no additional details were provided. The device was recently removed and replaced to address the issue, and no further adverse effects were reported. The device is expected to be sent for analysis, although it has not yet been received.

Während eines Verhörs in der Klinik wurde eine Episode von übermäßig wahrgenommenem Lärm beobachtet. Die technischen Dienste wurden kontaktiert und bestätigten, dass schlechte Telemetrie die Ursache sein könnte. Der Patient sollte am nächsten Tag zu einem Nachsorgetermin kommen, aber es wurden keine weiteren Details genannt. Das Gerät wurde kürzlich entfernt und ersetzt, um das Problem zu beheben, und es wurden keine weiteren Nebenwirkungen gemeldet. Es wird erwartet, dass das Gerät zur Analyse geschickt wird, obwohl es noch nicht eingegangen ist.

IQVIA use of on-demand Natural Language Processing (NLP AI) for translations to advance end user efficiency.

The life sciences industry faces numerous complexities across safety, regulatory, and quality functions. For instance, the scope of a quality certificate encompasses quality, regulatory, and safety aspects. Therefore, an organization cannot obtain certification, such as ISO 13485, unless its quality system incorporates safety processes and regulatory procedures for documentation, adverse event reporting, recalls, and more. Operational execution requires that all 3 areas fall within the scope of a quality certificate for an organization to enter the sector. To address these challenges, IQVIA offers comprehensive and integrated quality, regulatory and safety solutions and services. It is the first company to offer intelligently connected integration for all quality, regulatory and safety processes across healthcare, accelerating digital transformation through Software-as-a-Service (SaaS) and intelligence-driven simplification, automation, and integration of functions, processes, and systems, as opposed to other solutions that lack such wide-ranging functionality. For instance, SmartSolve connects with the

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- Sankara Narayanan, Industry Director safety and surveillance environment, as well as regulatory frameworks, driving safety, regulatory, and quality workflows and automation.

IQVIA regulatory and quality solutions digitalize regulatory and quality processes. By streamlining the end-to-end activities of QARA across organizations, businesses can bring products to market and maintain their presence. However, QA and RA often operate as separate disciplines, leading to significant duplication of work. IQVIA addresses this issue by providing an end-to-end solution, delivering value across the entire organization rather than focusing solely on individual pillars.

Within the regulatory and quality sphere, IQVIA provides an ecosystem comprising approximately 18

modules, including design control, change management, document management, complaint management, and supplier management. Additionally, the company provides data mining capabilities with tools like Vigilance Detect, which employs AI and NLP for literature and social media monitoring. IQVIA integrates these solutions to enable healthcare organizations to adopt a modular and scalable approach to end-to-end solutions.

Different organizations have different requirements depending on product type, route to market, and organizational maturity. IQVIA's ecosystem of solutions and modules allows the company to listen to the customer's problem statement, understand the workflows that need improvement, and identify data and decision points that require attention and their frequency of address. Then, IQVIA provides tailored solutions with the customer at the center of the process. Al allows IQVIA to streamline workflows, drive automation to connect process improvements, and provide insights into individual activities. Operational improvements focus on patient safety and enhance commercial performance.

IQVIA's AI strategy centers on accelerating user activities and simplifying processes. However, QARA professionals tend to be conservative and are not yet fully ready for total hands-off AI solutions. To address this issue, IQVIA provides numerous recommendation engines, which are very well accepted within the framework of IQVIA's end-to-end strategy across its solutions.

Customer Ownership, Purchase, and Service Experience

EQMS vendors have embarked on significant AI development efforts in complaints management and adverse event reporting, leveraging the abundance of data available from public domains. This focus is driven by high demand from customers, particularly in areas like complaints management and adverse event reporting, where organizations seek AI assistance to enhance accuracy and consistency. A notable feature of IQVIA's eQMS solution is its ability to integrate with other parts of the ecosystem. An important initiative undertaken by IQVIA'S eQMS product team is leveraging IQVIA Vigilance Detect, a data mining tool capable of extracting insights from both structured and unstructured content. By scanning social

media platforms, monitoring customer service inboxes, and listening to call center audio files, this technology identifies language patterns across numerous languages, flagging product quality issues or adverse events for human review. Vigilance Detect mitigates the risk of human fatigue as its algorithms execute on a regular basis, while humans still retain control to agree or disagree with flagged items and provide feedback to the AI engine, improving its performance over time. It is a great solution for adverse event reporting, helping organizations with remediation activities, particularly in cases of high-volume adverse events requiring quick capture. Organizations can use this AI tool to achieve substantial advancements in global quality compliance. Therefore, the power of AI serves as both a remediation tool and as a component that embeds in stronger processes, such as adverse event reporting.

Supporting industry professionals in enhancing patient outcomes is the top priority of this AI vendor. IQVIA considers that a commercial focus on quality management systems must align with delivering better and safer patient care. To illustrate the benefits of its AI to senior management, IQVIA emphasizes 4 key aspects: top-line growth, operational effectiveness, operational efficiency, and compliance. IQVIA's commitment to a single source of truth guarantees transparency, ensuring that the right product of the right quality reaches the right sector or customer at the right time. This facilitates predictable top-line growth and minimizes stockouts due to recalls and product quality concerns, allowing organizations to maintain their industry presence. Operationally, the IQVIA ecosystem standardizes and harmonizes processes, improves right-first-time activities, and optimizes resource utilization by removing manual integrations across different solutions from different providers. This enhances both operational effectiveness and efficiency, with AI playing a crucial role in workflow optimization. Moreover, as organizations strive to bring products to market and optimize connectivity, efficiency, and AI, compliance becomes a focal point. Frost & Sullivan recognizes the value proposition of IQVIA's regulatory and quality solutions, highlighting their significant benefits in enhancing an organization's commercial performance and professional activities.

Device Problem Code Assistant						
Term	IMDRF Code	FDA Code	Confidence %	Confidence Level		
Over-Sensing	A070909	1438	93.78%			
Signal Artifact/Noise	A090801	1036	35.63%			
Interrogation Problem	A0711	4017	11.20%	•		
Pacing Problem	A0712	1439	10.42%	•		

IQVIA use of Machine Learning and NLP on adverse events to recommend appropriate problem codes.

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- Sankara Narayanan, Industry Director IQVIA does not merely offer an AI solution to its customers—it understands that the key is not implementing generative AI everywhere but offering the right AI solution designed to understand workflow, data, privacy, availability, and the need to codify certain information correctly for effective AI operation. With its solutions being deployed at multiple sites around the world, IQVIA works closely with customers to ensure an optimal service experience. It regularly contacts customers to remain abreast of their needs and ensures that they have the latest versions of its solutions.

Concerning AI solutions, IQVIA addresses several key questions. The first question is relevance: Is the technology relevant to QARA professionals and aligned with globally mandated processes, procedures, documents, and data required by regulations and

with globally mandated processes, procedures, documents, and data required by regulations and standards, rather than merely being technology-driven? In response, IQVIA's solutions support all activities of QARA professionals, aligning data, documents, workflow, analytics, and reporting with the regulatory and standard requirements that drive the global solutions for QARA professionals' end-to-end quality management. The second question revolves around compliance: Is the solution controlled? Depending on the type of solution, IQVIA ensures varying levels of validation and compliance with other Al regulations, such as the European Al Act (EU AIA), which is recently coming into force. The third question is cost-effectiveness: Is the solution economically viable and affordable? QARA professionals must be empowered to navigate a complex environment for complex products in a cost-effective way. IQVIA closely aligns with its customers' needs. While the company's solutions add incredible value, IQVIA is careful to ensure they do not become cost prohibitive. As a healthcare company, IQVIA prioritizes providing safe, effective, and financially savvy healthcare solutions rather than simply chasing technological advancements. IQVIA explores AI solutions, integrating them into workflows while assessing the volume of data needed for effectiveness. The company develops solutions that are cost-effective and enable organizations to optimize their resources, allowing them to focus more on patient safety and commercial growth activities.

Overall, IQVIA adopts a customer-centric approach, considering the level of AI adoption a customer is prepared for and tailoring solutions to the specific use case. IQVIA begins by understanding the customer's business context, products, route to market, maturity level, significant workflows, and areas of risk or opportunity. Then, the company analyzes the data and proceeds with solutioning, offering modular and scalable alternatives that provide flexibility for the customer.

Human Capital and Brand Equity

An advantage of IQVIA is its employees, who have extensive experience in the life sciences industry throughout their careers. They understand their customer base and meticulously advise on AI applications to ensure that IQVIA safeguards their decisions, compliance, and data.

Customers choose a vendor not only for the best quality management system, but also for the vendor's capacity to enhance commercial performance by reducing safety events, ensuring timely adverse event reports, prioritizing patient safety, fostering commercial growth, and managing regulator relationships. IQVIA excels in meeting these customer expectations.

Conclusion

Healthcare organizations need AI solutions tailored to their highly regulated industry environment. IQVIA successfully meets this demand. The company's combination of consulting, outsourcing, and technology solutions transforms healthcare and support industry professionals in improving patient outcomes. IQVIA's AI solutions digitalize regulatory and quality processes. The company's value proposition enables top-line growth, operational effectiveness, efficiency, and compliance, all of which significantly boost companies' commercial performance and professional activities. IQVIA's relevant, controlled, and cost-effective AI solutions further enhance its customer value proposition. The company has proven that a comprehensive focus on patient safety, patient care, and commercial performance is possible. Through right-first-time activities and a single source of truth, IQVIA tackles the increasing complexities of global regulations, optimizes resource allocation to achieve the set financial performance, and provides strategies for complex healthcare challenges. Frost & Sullivan applauds IQVIA's customer-centric approach.

With its strong overall performance, IQVIA earns Frost & Sullivan's 2024 Global Customer Value Leadership Award in the AI regulatory and quality solutions space for the healthcare industry.

What You Need to Know about the Customer Value Leadership Recognition

Frost & Sullivan's Customer Value Leadership Award recognizes the company that offers products or services customers find superior for the overall price, performance, and quality.

Best Practices Award Analysis

For the Customer Value Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at http://www.frost.com.

The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator $^{\text{TM}}$.

Learn more.

Key Impacts:

- **Growth Pipeline:** Continuous Flow of Growth Opportunities
- **Growth Strategies:** Proven Best Practices
- Innovation Culture: Optimized Customer Experience
- ROI & Margin: Implementation Excellence
- Transformational Growth: Industry Leadership

OPPORTUNITY UNIVERSE Capture full range of growth opportunities and prioritize them based on key criteria OPPORTUNITY EVALUATION Adapt strategy to changing market dynamics and unearth new opportunities OPPORTUNITY EVALUATION Conduct deep, 360-degree analysis of prioritized opportunities ENGINETM GO-TO-MARKET STRATEGY Translate strategic alternatives into a cogent strategy

The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.

Analytical Perspectives:

- Mega Trend (MT)
- Business Model (BM)
- Technology (TE)
- Industries (IN)
- Customer (CU)
- Geographies (GE)

