2024 World Class Regulatory Information Management Study White Paper

Based on our *2024 World Class RIM℠: Extending the Power of RIM* (n = 63)

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Introduction

Our biennial World Class Regulatory Information Management (RIM) study focused this cycle on extending the power of RIM. Most companies have modernized their global regulatory processes and systems and are now optimizing to fully realize the benefits of time to market, efficiency, and productivity.

This paper reviews key learnings from the 2024 study, including industry performance status, investment priorities, strategic data management, regulatory digital strategy status, advanced technology application, and the software provider landscape. The paper also highlights the practices of our 22 top performers: those achieving strong performance or world class levels. Key study takeaways include:

- There has been a substantial increase in overall industry performance since our 2022 study, and for the first time in our study history, all five performance dimensions have increased.
- The study's top performers continue to outperform other study participants in key performance indicators (KPIs) such as RIM capability efficiency, tangible benefit realization, time to access information, and data quality levels. They also excel in metric-driven continuous improvement, are better at implementing and executing change, and have a right-the-first-time mindset.
- Most companies are investing to mature their digital programs and are also increasing artificial intelligence and automation proof of concepts with very few moving into production.
- There is a clear correlation of mature data governance practices with high data quality levels, but no correlation of a company's date entry model to high data quality levels.
- End user accountability of data is a core challenge for most study participants.

The paper's information and graphs are based on our 2024 World Class RIM study (n = 63), client work, and our insights. The paper's structure is as follows:

- Survey Demographics and Design Strategy
- Regulatory Investment Priority and World Class RIM Performance Status
- Organizational Practices Strengthen Culture, Teams, and Workforce Capabilities
- Data Quality Confidence Status and Evolving Data Governance Practices
- Strategic Data Management and RIM Connection Points
- Advanced-Technology Maturity and Investment Priorities
- Software Provider Landscape Summary
- Study Conclusion

We hope you find the information insightful and valuable. Please contact us with any questions.

Survey Demographics and Design Strategy

This is our seventh large RIM study since 2013 that enables us to track and provide unique trending data across the regulatory space for industry. The respondents represent large, midtier, small, and very small organizations (Figure 1) whose tier sizes are informed by *Pharmaceutical Executive*'s annual list of top 50 companies by revenue. For the first time, our study includes participation by all but one company in *Pharmaceutical Executive*'s top 25. We analyzed the data to uncover unique insights and trends by company tier size and top performers.

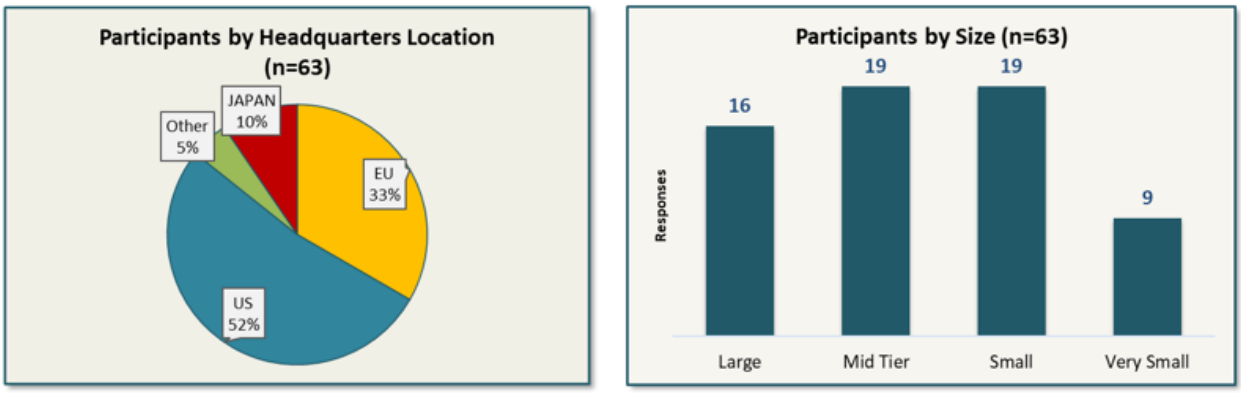


Figure 1: 2024 Survey Demographics

Another key demographic is product portfolio, which enables us to perform various analyses based on product type and number of products. Figure 2 depicts the product mix of the 63 participating companies by tier. We have noticed a steady increase in the percentage of study participants that have combinational products requiring capabilities from both the medical technology and biopharmaceutical sectors.

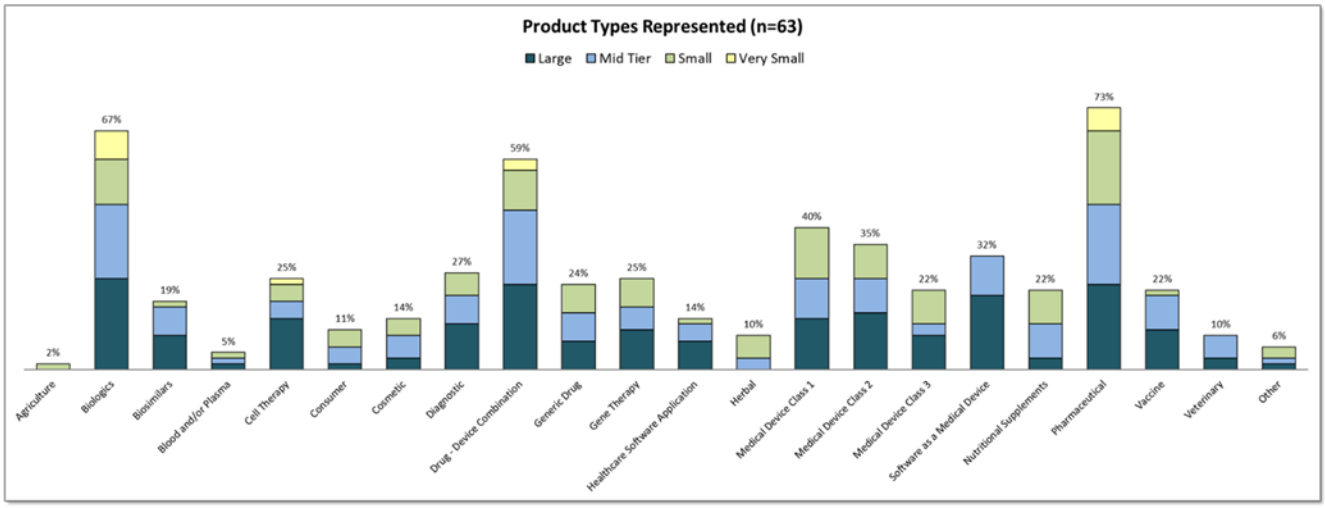


Figure 2: 2024 Product Type Demographic

We appreciate the 71 individuals who are industry experts, regulatory professionals, and thought leaders, along with our partners and study advisers, who contributed to strengthening the survey design in fall 2023. In total, 44 unique companies representing industry and prominent regulatory software and

solution providers participated in seven global design sessions in Zurich, London, Copenhagen, Chicago, San Francisco, Boston, and Lambertville, New Jersey.

Regulatory Investment Priority Status

The RIM transformation period, which started around 2015, is ending its decade-long cycle, as most companies have completed modernization of their RIM capabilities and are now looking forward to increased business benefit realization through optimization activities. For 2024, we added an analysis dimension to learn what was contained in recent business cases for RIM modernization or transformation projects. Table 1 reviews the top business case elements compared with top business benefit outcomes by size of company. It turns out that reduction in operational complexity was the number one business case goal regardless of company size. Our consulting experience informs us that this goal is typically a combination of system consolidation, process standardization, and strategic data management.

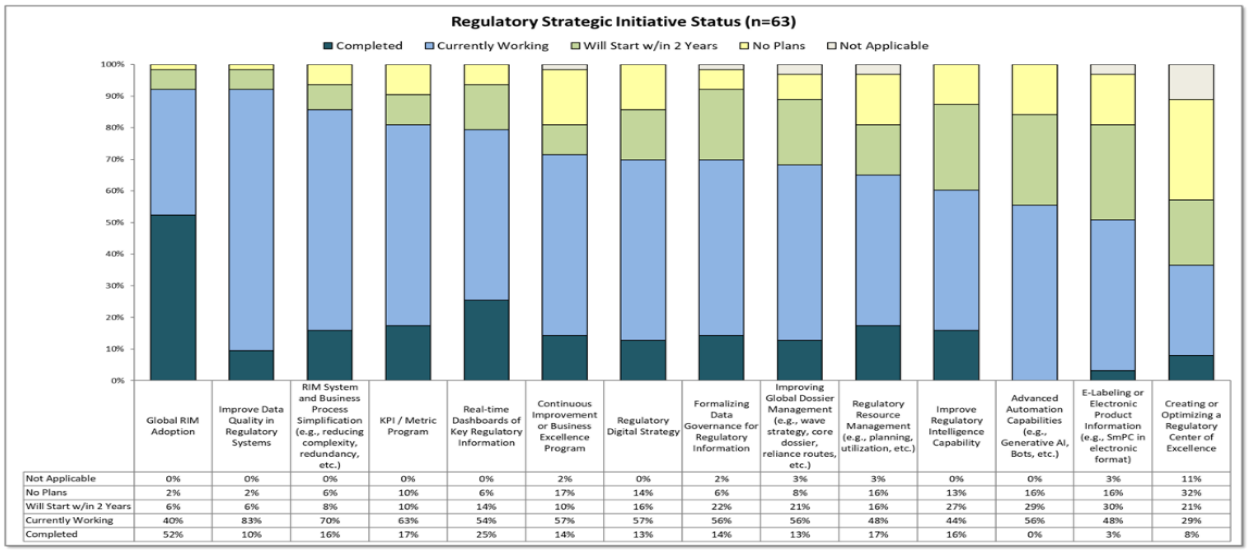
Dimension	Large Tier (n = 16)	Mid Tier (n = 19)	Small / Very Small Tier (n = 28)
Top Business Case Elements	1) Increase user productivity / efficiency (69%) 2) Improve data quality (69%) 3) Access to real time information (63%) 4) Better integration of business process (63%) 5) Improve compliance / reduce risk (63%) 6) Improve information exchange with other functions (63%) 7) Reduce operational complexity (63%) 8) Simplify local affiliate interactions (63%)	1) Reduce operational complexity (68%) 2) Access to real time information (58%) 3) Better integration of business process (58%) 4) Enhance user experience (53%) 5) Improve data quality (53%)	1) Reduce operational complexity (57%) 2) Improve compliance / reduce risk (50%) 3) Improve data quality (50%) 4) Better integration of business process (46%) 5) Increase user productivity / efficiency (46%)
Top Business Benefit Outcomes (fully + partially achieved)	1) Access to real time information (81%) 2) Improved audit / inspections (75%) 3) Improved data quality (75%) 4) Improve compliance / reduce risk (75%) 5) Speed to regulation change (75%)	1) Access to real time information (74%) 2) Improve compliance / reduce risk (68%) 3) Improve data quality (68%) 4) Reduce operational complexity (68%)	1) Improve compliance / reduce risk (79%) 2) Access to real time information (75%) 3) Improve data quality (75%) 4) Improve information exchange with other functions (64%)

Please note: Some participants did not have a recent business case resulting in many benefit outcomes exceeding the business case percentages

Table 1: Business Case Elements and Business Benefit Outcomes

End-to-end (E2E) process work continues its progression for many cross-functional business processes. The top-performer cohort is generally ahead, with an average of 45% reporting they recently completed E2E process work such as aggregate safety reporting (64% completed) and new regulatory requirement impact assessments (59% completed) compared with an average of 21% of all other companies. Reduction in operational complexity remains a key driver in the optimization of most of the E2E processes tested, including structured data submission (51% currently working on); chemistry, manufacturing, and control (CMC) change control (38% currently working on); and health authority (HA) correspondence management (38% currently working on).

Figure 3 summarizes the status of key regulatory strategic initiatives with 52% of all companies reported their global RIM adoption complete, which is a dramatic increase compared with 2020 (27% complete) and 2022 (32% complete).



	Global RIM Adoption	Improve Data Quality in Regulatory Systems	RIM System and Business Process Simplification (e.g., reducing complexity, redundancy, etc.)	KPI / Metric Program	Real-time Dashboards of Key Regulatory Information	Continuous Improvement or Business Excellence Program	Regulatory Digital Strategy	Formalizing Data Governance for Regulatory Information	Improving Global Dossier Management (e.g., wave strategy, core dossier, reliance routes, etc.)	Regulatory Resource Management (e.g., planning, utilization, etc.)	Improve Regulatory Intelligence Capability	Advanced Automation Capabilities (e.g., Generative AI, Bots, etc.)	E-Labeling or Electronic Product Information (e.g., SmPC in electronic format)	Creating or Optimizing a Regulatory Center of Excellence
Not Applicable	0%	0%	0%	0%	0%	2%	0%	2%	3%	3%	0%	0%	3%	11%
No Plans	2%	2%	6%	10%	6%	17%	14%	6%	8%	16%	13%	16%	16%	32%
Will Start w/in 2 Years	6%	6%	8%	10%	14%	10%	16%	22%	21%	16%	27%	29%	30%	21%
Currently Working	40%	83%	70%	63%	54%	57%	57%	56%	56%	48%	44%	56%	48%	29%
Completed	52%	10%	16%	17%	25%	14%	13%	14%	13%	17%	16%	0%	3%	8%

Figure 3: 2024 Regulatory Strategic Initiatives Status

Data quality improvement, system and process simplification, and KPI metric program implementation are the priority initiatives across the industry. Table 2 summarizes priority RIM capability near-term investments (within two years), E2E process-focused near-term investments, and strategic-initiative-focused near-term investments by tier cohorts.

Dimension	Large (n = 16)	Mid Tier (n = 20)	Small (n = 18)	Very Small (n = 9)
Top 2 RIM Capability Investments	1. Reporting, Analytics and Dashboards 2. Product Registration Management	1. Reporting, Analytics and Dashboards 2. Product Registration Management	1. Reporting, Analytics and Dashboards 2. Product Registration Management	1. HA interactions 2. Global Submission Archive
Top 2 E2E Process Focus	1. Change Control – CMC Change 2. HA Correspondence Management	1. Change Control – CMC Change 2. Change Control – Label Management	1. Change Control – CMC Change 2. Change Control – Label Management	1. CTA/IND Process 2. HA Correspondence Management
Top 3 Strategic Initiative Focus	1. Improve DQ in systems 2. Process Simplification 3. Formalizing Data Governance	1. KPI Metric Program 2. Global RIM adoption 3. Process Simplification	1. Global RIM adoption 2. Improve DQ in systems 3. Process Simplification	1. Global RIM adoption 2. Improve DQ in systems 3. Process Simplification

CTA = Clinical Trial Application, DQ = data quality, IND = Investigational New Drug application

Table 2: 2024 Investment Priority by Tier Analysis

World Class RIM Performance Status

We created the World Class RIM performance model with 35 companies from 2015 to 2017. For 2024, we slightly expanded the number of key performance indicators, but the remainder of the performance model remained unchanged.

Figure 4: World Class RIM Categories

World Class RIM: 5 Elements, 11 Questions

The following describes the core five World Class RIM categories (Figure 4) with the number of data points (in parentheses) used for this industry benchmark.

1. **Data Quality Confidence (11):** It's one thing to have an authoritative source, but what is your level of confidence in the quality of your authoritative source's data? This category is heavily weighted in our world class algorithm and is foundational to RIM performance.
2. **Business Benefit Realization (50):** This category comprises 15 business benefit realization statuses, 23 key performance metric usages (out of a possible 31), continuous improvement program characteristics, and operating cost understanding.
3. **Global Reach: Global System Deployment Status (8):** *World Class* means that the world can access and use the core RIM capabilities in at least 75% of affiliate offices (we account for the agent/distributor network).
4. **Level of Efficiency (18):** This category evaluates the effective use of resources, the repeatability of process, and low error rates to achieve the regulatory goals of the 15 RIM capabilities, data standards, and three connection points: electronic trial master file (eTMF), enterprise-resource-planning (ERP) system, and quality management system (QMS). We use a four-point scale so that participants who are unsure must decide whether they lean toward efficient or not efficient.
5. **Time to Report Information: Provide Accurate Reporting for Common Regulatory Questions (9):** This is a very telling measure, with clear correlation with data-quality confidence levels. We ask nine common regulatory questions—for example, What products are registered in what countries? And participants indicate whether they can answer each question in real time, or within a day, or within multiple days, or within a week or more.

Figure 5 depicts the placement of the 63 participants and their relationships to their tier averages, the strong-performance band, and the World Class level. One company continues with its World Class rating, and 21 are in the strong-performance band. All tiers experienced performance improvement in 2024; the midtier, small, and very small tiers experienced significant improvement; and the large tier experienced incremental performance improvement.

Individual company plot is determined by 11 study questions listed below

- **Operational Performance**
  Q16 - RIM Capability Efficiency
  Q26 - System Connectivity
  Q23 - Time to Report Information
  Q25 - Data Quality Confidence
- **Business Benefit Outcomes**
  Q17 – Business Case and Benefit Results
- **Foundational Dimensions**
  Q18 - Metric Characteristics
  Q19 to 21 - Volume, Cycle Time, and Quality Metrics
  Q22 - Understanding Cost
  Q24 - Global Reach

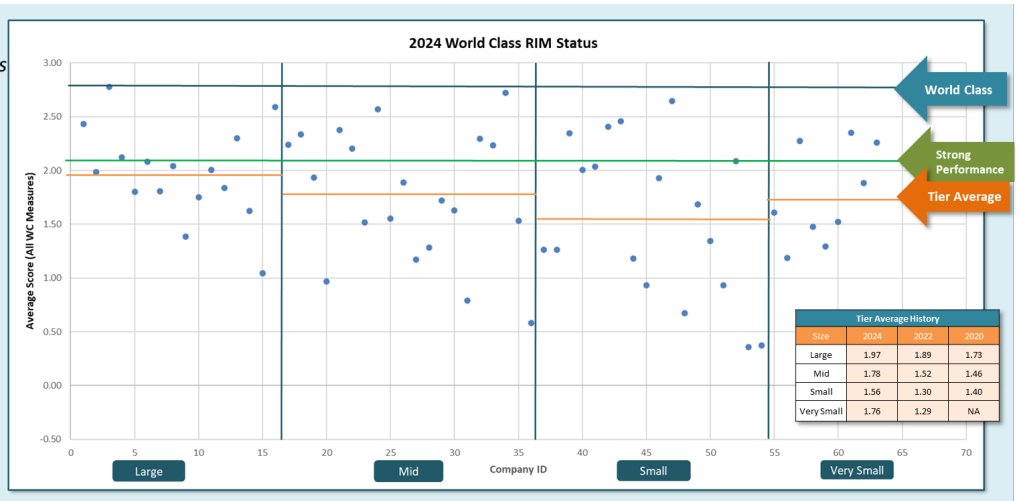


Figure 5: World Class RIM Benchmark Results

We see the group of top performers as a predictor of future industry performance, and Table 3 depicts seven key dimensions, or indicators, of top-performing organizations. Our data shows the direct correlation of our cohort of top performers (n = 22) with better outcomes across multiple performance dimensions and tangible business benefits achieved, such as the fact that 86% of top performers have strong RIM capability efficiency compared with just 51% of everybody else (n = 41); and 77% of top performers are achieving the business benefits of reducing time to health authority submissions in primary markets compared with just 32% of everybody else. The overall message of that comparison shows what is possible for the everyone-else cohort!

Performance Dimension	Top Performers	Everybody Else
Capability Efficiency (15 RIM capabilities)	86%	51%
Data Quality "High Confidence"	63%	38%
Business Outcomes	77%	45%
Metrics Driven Continuous Improvement (% who have it)	100%	72%
Metric Program is Effective	95%	34%
Real Time Information	68%	38%

Tangible Benefit Comparison	Top Performers	Everybody Else
Reduce Operational Complexity	73%	54%
Reduce time to Health Authority submission - Primary Markets	77%	32%
Reduce time to Health Authority submission – Secondary Markets	55%	24%
Reduce Operating Cost	83%	39%
Maximize Resource Value - resource reallocation to higher value work	77%	22%

Table 3: Top Performers versus Everybody Else Performance Comparison

Organizational Practices Strengthen Culture, Teams, and Workforce Capabilities

Our RIM Path to High Performance Framework (Figure 6) was first introduced in 2020 to model the way we view the relation between having the ability to maximize business benefits and the application of key organization and foundational practices. Since 2014, no correlation has been found between study top performers and any one system strategy or partnering with a specific software provider; instead, performance improvement happens as intention and efforts get applied consistently to strengthening the organization's foundational elements and maturing process levels to fully leverage technology investments. Simply put, the stronger an organization is with regard to its organizational components coupled with mature and standard processes—the more value is received from technology investment and therefore higher business benefits.

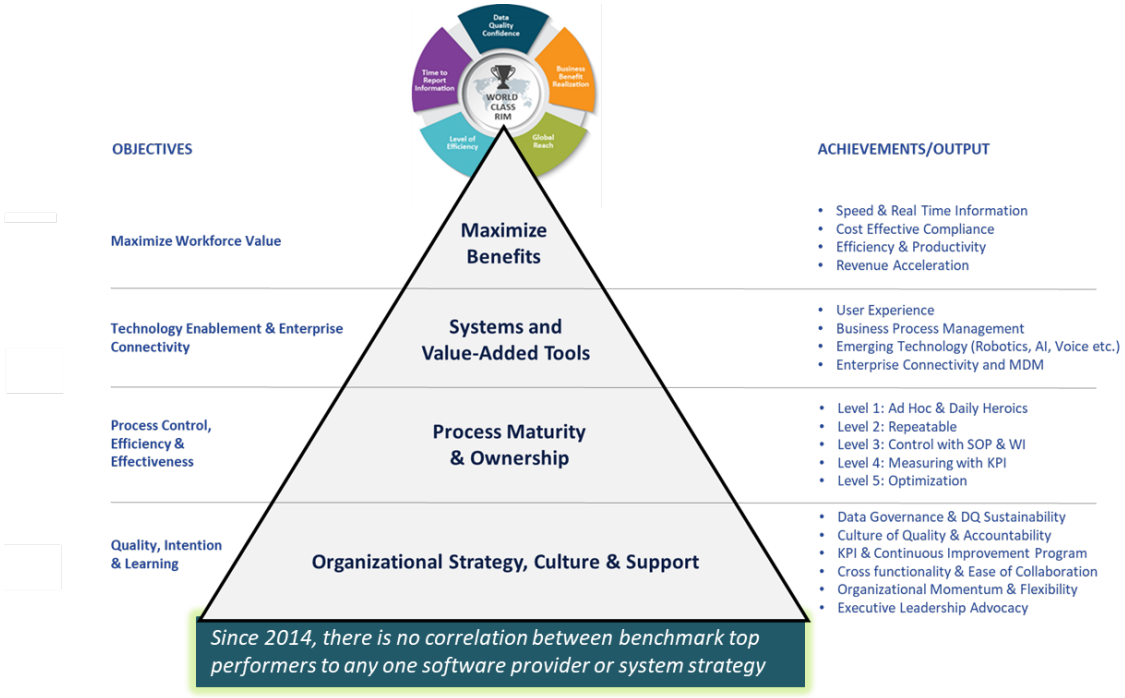
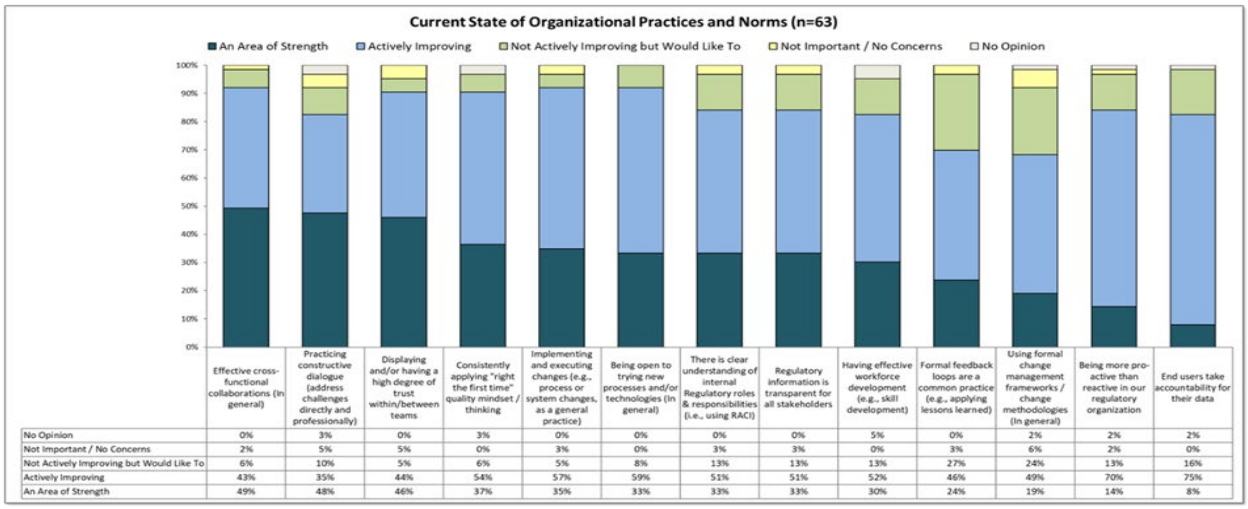


Figure 6: Path to High Performance Model

That direct correlation continues even when we examine data not used in the calculation of each participant's World Class RIM study rating. In the 2022 World Class RIM study, we challenged ourselves to include questions about company norms, practices, and organizational strategies. It was our first attempt to benchmark culture because we appreciate that culture heavily affects companies and their workforces. We originally structured the questions to reveal regulatory organizations' general sentiments about their company culture (e.g., Do you agree or disagree that your company is viewed as an industry leader?). We found the results to be more aspirational, so for 2024, we restructured the question to ask about active work and effort investment in those similar organizational practices and norms. Figure 7 shows—across 13 different practices or characteristics of a regulatory organization—data on areas organizations are actively improving, areas they are currently strong in, and areas in which they have no

active engagement.



	Effective cross-functional collaborations (In general)	Practicing constructive dialogue (address challenges directly and professionally)	Displaying and/or having a high degree of trust within/between teams	Consistently applying "right the first time" quality mindset / thinking	Implementing and executing changes (e.g., process or system changes, as a general practice)	Being open to trying new processes and/or technologies (In general)	There is clear understanding of internal Regulatory roles & responsibilities (i.e., using RACI)	Regulatory information is transparent for all stakeholders	Having effective workforce development (e.g., skill development)	Formal feedback loops are a common practice (e.g., applying lessons learned)	Using formal change management frameworks / change methodologies (In general)	Being more pro-active than reactive in our regulatory organization	End users take accountability for their data
No Opinion	0%	3%	0%	3%	0%	0%	0%	0%	5%	0%	2%	2%	2%
Not Important / No Concerns	2%	5%	5%	0%	3%	0%	3%	3%	0%	3%	6%	2%	0%
Not Actively Improving but Would Like To	6%	10%	5%	6%	5%	8%	13%	13%	13%	27%	24%	13%	16%
Actively Improving	43%	35%	44%	54%	57%	59%	51%	51%	52%	46%	49%	70%	75%
An Area of Strength	49%	48%	46%	37%	35%	33%	33%	33%	30%	24%	19%	14%	8%

Figure 7: 2024 Status of Organizational Practices and Norms

The goals were to learn where most organizations' priorities lie and whether there were areas that most regulatory organizations across industry are currently working on. The results showed that (1) 49% of companies reported their organizations are strong in conducting effective cross-functional collaborations, (2) 48% are good at addressing challenges directly and professionally by practicing constructive dialogues, and (3) 46% indicated high degrees of trust among their teams. Those top three areas of strength contribute to a healthy workplace environment and speak to the importance of psychological safety. Regardless of tier size, performance level, or product portfolio, though, we also found that most organizations are actively working to have their end users take accountability of their data (75%) and becoming more proactive than reactive in their regulatory organization (70%). The top two practices that organizations reported they would like to improve on but are *not* actively pursuing are the incorporation of feedback loops as a standard practice (27%) and the use of formal change management frameworks and methodologies (24%). Initial steps for both of those practices are not complex and can be easily incorporated by means of common practice guides and developed tools that are widely available.

The correlation of top-performing organizations with specific practices and strategies can be easily detected in a comparison of areas of strength (for organizational practices) for the top performer cohort to everybody else (Figure 8).

Significant differences between top performers (TP) and everybody else (EE) (% of respondents for areas of strength) are as follows:

- Implementing and executing change: 68% TP versus 17% EE
- Right-the-first-time mindset: 64% TP versus 22% EE
- Clear roles and responsibilities: 59% TP versus 20% EE
- Transparent information: 55% TP versus 22% EE
- Effective workforce development: 50% TP versus 20% EE

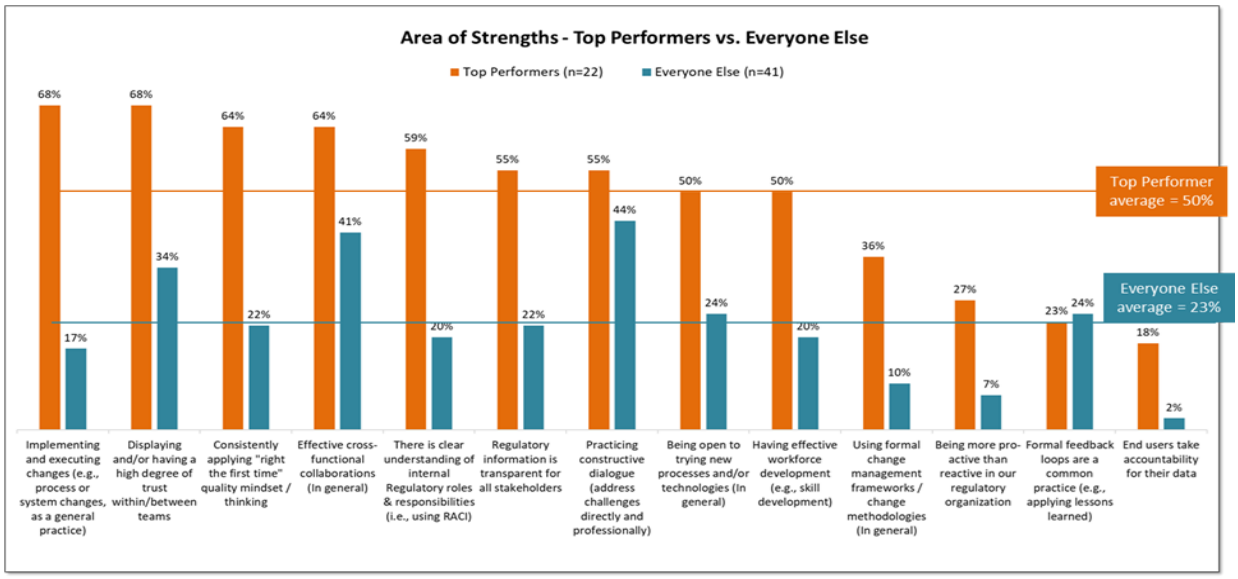


Figure 8: Areas of Strength for Top Performer versus Everybody Else: Organizational Practices

Strengthening the five areas that showed significant differences between strong-performing organizations and all others also supports the same foundation for having effective data governance, which is another key area we believe leads to efficiency gains by enabling and sustaining high data quality.

Along with consistently applying critical organizational practices, investment in workforce skills and capabilities is another organizational strategy the study explored. In the past few years, we've noticed an increased interest in data-related skill sets and capabilities such as data-governance-related roles, data scientists, and data stewards. Most organizations today report having access to those roles' skills and capabilities either directly in regulatory or within their broader organization (Table 4). For example, in 2022, only 38% of organizations reported having data governance roles versus 46% reported today.

Heat Map for Regulatory Capabilities / Skills (n=63)	Currently have in Regulatory	Have access in the broader organization	Are or will upskill employees	Are or will hire in the next 2 years	Are or will use external talent
Data Architecture	27%	54%	27%	11%	13%
Data Governance	46%	35%	37%	10%	10%
Data Stewardship	48%	29%	30%	11%	11%
Data Management	71%	22%	19%	10%	14%
Data Strategy and Planning	37%	49%	22%	5%	19%
Global Data Privacy Policy (GDPR)	17%	63%	6%	3%	6%
Business Excellence Capability	63%	56%	22%	8%	10%
Organization Change Management Skills	49%	54%	24%	2%	22%
Automation Design and Delivery Skills	29%	46%	21%	6%	21%
Structured Data Submission Capability	52%	22%	46%	11%	17%

Table 4: Status of Regulatory Workforce Capabilities and Skills

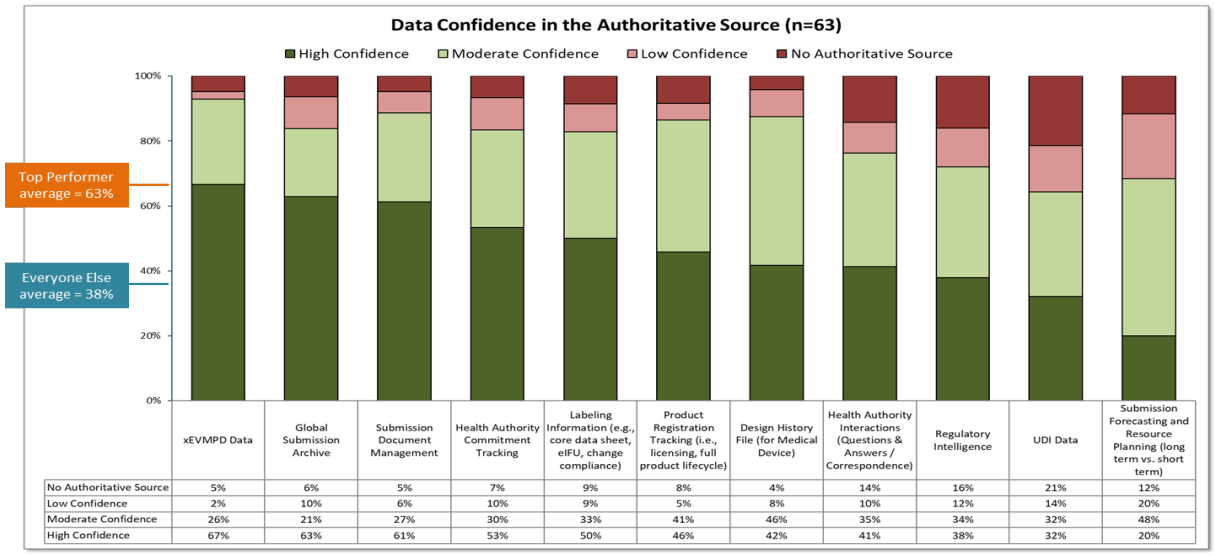
Forty-six percent of companies report upskilling plans are in place for their workforce for structured data submission capability, 37% for data governance, and 30% for data stewardship. Upskilling strategies require knowledgeable change management capabilities and solid workforce development resources, which are two areas that many companies are currently trying to improve. E2E process thinking, cross-

functional collaborations, and proficiencies in technologies remain the future-ready core competencies for regulatory workforces as organizations continue their journeys to accelerate business value realization, mature their digitization strategies, and better manage data quality sustainability.

Data Quality Confidence Status and Evolving Data Governance Practices

We have been tracking data quality confidence since 2014, and it remains a key component of our World Class RIM rating calculation. Confidence in data quality is a major indicator of the true effectiveness of regulatory processes and systems: an organization that has confidence in its data has established processes and capabilities in support of the management of that data that are strong and trusted by the organization.

Industry continues to struggle with quality of data from designated authoritative sources, as seen in Figure 9; and when we look at the responses across all categories, we see an aggregate high-confidence score of 47%, which is much higher than 2022's aggregate score of 38% and 2020's of 33%.



	xEVMPD Data	Global Submission Archive	Submission Document Management	Health Authority Commitment Tracking	Labeling Information (e.g., core data sheet, eIFU, change compliance)	Product Registration Tracking (i.e., licensing, full product lifecycle)	Design History File (for Medical Device)	Health Authority Interactions (Questions & Answers / Correspondence)	Regulatory Intelligence	UDI Data	Submission Forecasting and Resource Planning (long term vs. short term)
No Authoritative Source	5%	6%	5%	7%	9%	8%	4%	14%	16%	21%	12%
Low Confidence	2%	10%	6%	10%	9%	5%	8%	10%	12%	14%	20%
Moderate Confidence	26%	21%	27%	30%	33%	41%	46%	35%	34%	32%	48%
High Confidence	67%	63%	61%	53%	50%	46%	42%	41%	38%	32%	20%

Figure 9: Data Confidence Summary

What became very clear in 2024 is the direct correlation of mature data governance practices with high data quality levels and the fact that there is no correlation of a company's data entry model with high data quality levels. We were not surprised to find how our top performer cohort has significantly greater maturity in data governance practices (Figure 10), with a resulting 63% aggregate high data quality average compared with a 38% aggregate high data quality for the everybody else cohort. Our eight key data quality practices as shown in Figure 10 are based on six years of working with large multinational, midtier, and smaller organizations to implement and optimize data governance models and practices.

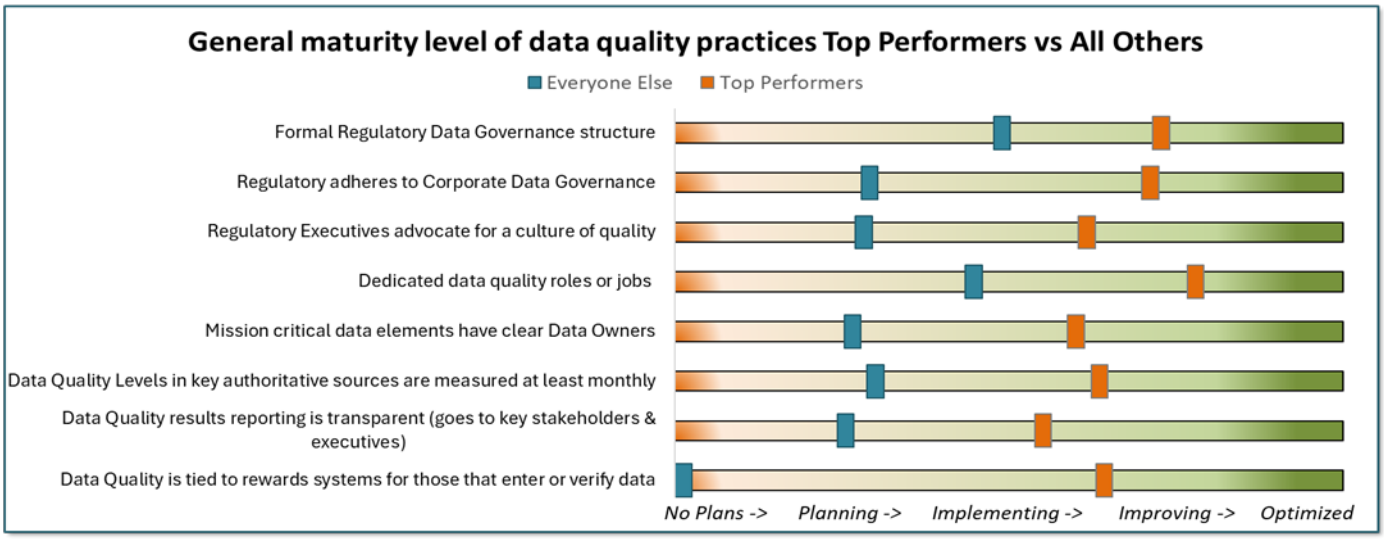


Figure 10: Data Quality Practice Maturity

We believe that effective data quality and data governance programs will prove to be key elements in moving the needle on data quality confidence, and because of the demands of structured data submissions, we anticipate that more and more organizations will be launching efforts to implement these capabilities. In fact, 83% of study participants are actively working to improve data quality levels, and 56% are actively working to formalize their data quality governance programs.

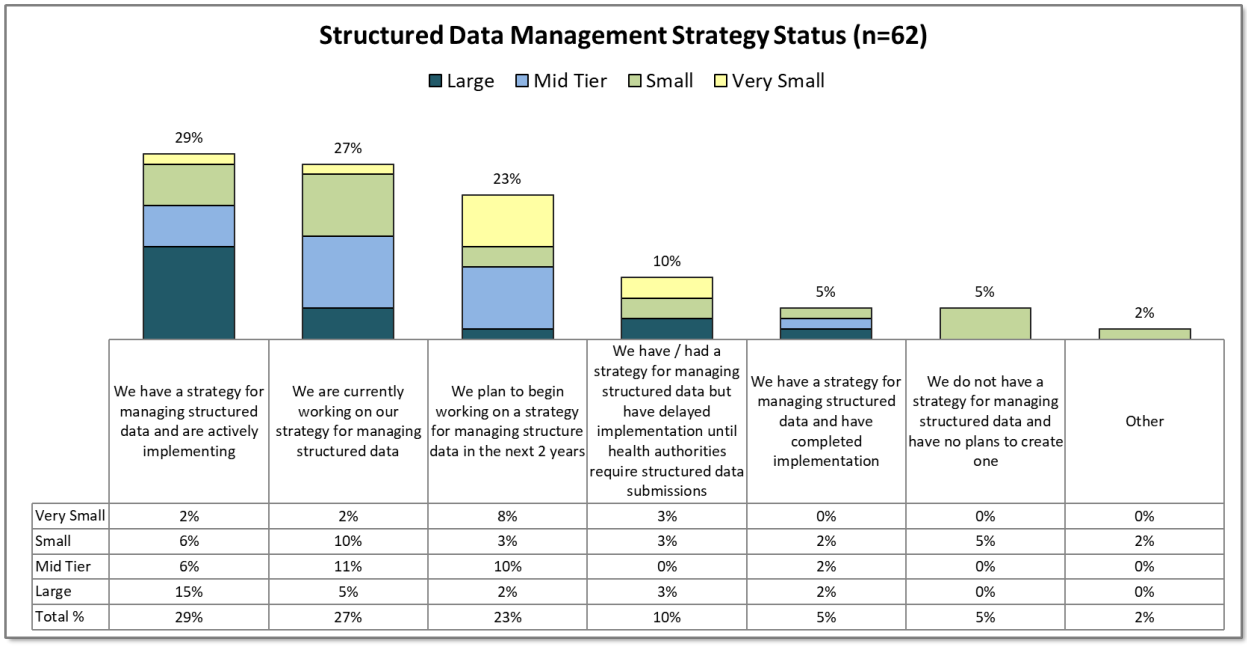
Many of the elements in a data governance program must be consistent between both systems and functions. Figure 11 shows the Beczek–Gens model wherein the two groupings of elements must find balance in order to realize a mature data governance program. In our opinion, it's that balance between the operational work (processes and capabilities) and the cultural work (institutionalization) that makes a data governance program successful or not.

Figure 11: Finding Balance for a Mature Data Governance Program

Strategic Data Management and RIM Connection Points

In 2020, we introduced a section in the World Class RIM study that focused on Identification of Medicinal Products/Substance, Product, Organization, and Referential (IDMP/SPOR) implementation by surveying respondents' implementation approaches and statuses. In 2022, we included the IDMP/SPOR section again, but during the interval, the European Medicines Agency did a bit of an about-face when suddenly, the requirement to include a structured Fast Healthcare Interoperability Resources (FHIR) standard message within electronic Common Technical Document (eCTD) submissions—got put on the back burner in favor of the new, Web-based electronic Application Form. Two years after the dust has cleared somewhat, it has become clear that even though the FHIR message requirement has been set aside indefinitely, its impact on regulatory remains: industry has embarked on a journey focused on establishing and improving structured data and system connectivity. In recognition of that, our 2024 study changed the focus of the former IDMP/SPOR section to more broadly cover structured data management.

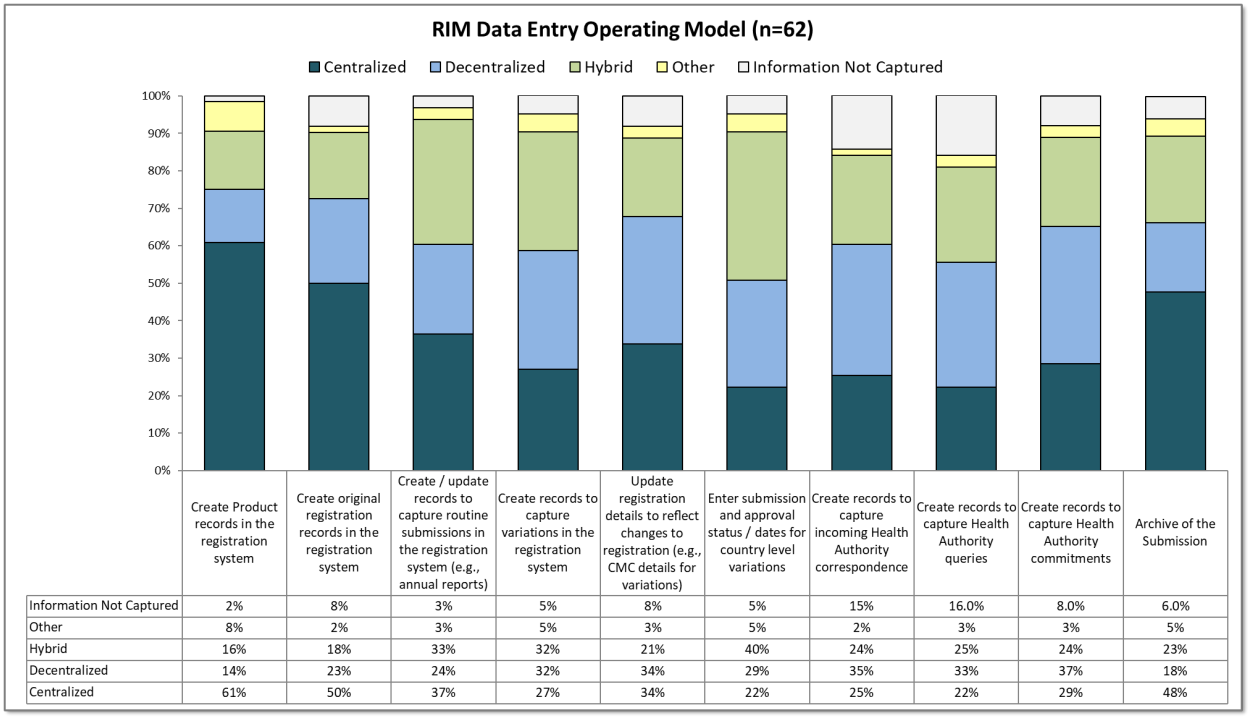
Overall, industry is taking structured data management seriously, as shown in Figure 12, with 34% of organizations reporting they have strategies for managing structured regulatory data and are either actively implementing (29%) or have completed implementation (5%). Half of respondents report they are currently working on strategies to manage structured data (27%) or they plan to within two years (23%). We also asked what kinds of capabilities companies are implementing to support structured data management and found that more than half of the organizations surveyed have completed or are actively implementing data mapping of health authority reference data, have established or are establishing dedicated teams, and have updated or are updating existing systems and processes to manage structured data.



	We have a strategy for managing structured data and are actively implementing	We are currently working on our strategy for managing structured data	We plan to begin working on a strategy for managing structure data in the next 2 years	We have / had a strategy for managing structured data but have delayed implementation until health authorities require structured data submissions	We have a strategy for managing structured data and have completed implementation	We do not have a strategy for managing structured data and have no plans to create one	Other
Very Small	2%	2%	8%	3%	0%	0%	0%
Small	6%	10%	3%	3%	2%	5%	2%
Mid Tier	6%	11%	10%	0%	2%	0%	0%
Large	15%	5%	2%	3%	2%	0%	0%
Total %	29%	27%	23%	10%	5%	5%	2%

Figure 12: Structured Data Management Strategy Status

New to the survey this year is a question inspired by the reaction to one of our pulse surveys: RIM data entry and management responsibilities. We have had many discussions with companies about this topic through the years, and in our fall 2023 study design sessions, we determined how to provide a detailed analysis of data entry models; we landed on 10 specific data categories (Figure 13). We asked organizations to identify which roles are involved in managing each data category. Generally, the creation of core product and registration data is more likely to be centralized (61% and 50%, respectively), whereas the management of transactional data (variation and registration details and health authority interactions) is more likely to be decentralized or hybrid.



	Create Product records in the registration system	Create original registration records in the registration system	Create / update records to capture routine submissions in the registration system (e.g., annual reports)	Create records to capture variations in the registration system	Update registration details to reflect changes to registration (e.g., CMC details for variations)	Enter submission and approval status / dates for country level variations	Create records to capture incoming Health Authority correspondence	Create records to capture Health Authority queries	Create records to capture Health Authority commitments	Archive of the Submission
Information Not Captured	2%	8%	3%	5%	8%	5%	15%	16.0%	8.0%	6.0%
Other	8%	2%	3%	5%	3%	5%	2%	3%	3%	5%
Hybrid	16%	18%	33%	32%	21%	40%	24%	25%	24%	23%
Decentralized	14%	23%	24%	32%	34%	29%	35%	33%	37%	18%
Centralized	61%	50%	37%	27%	34%	22%	25%	22%	29%	48%

Figure 13: RIM Data Entry Operating Models

Additional analysis of both large (Table 5) and midtier participants found no correlation between data management models and data quality confidence levels. We also reviewed several key business benefit outcomes and also found no pattern of data entry to data quality levels to business benefits.

	Data Entry Model						Data Confidence	Benefits realized				
	Creat Product Records	Create Registration Records	Routine Submission Records	Variation Recods	Update Registration Details	Submission/Approval Status	Product Registration Data Confidence	Operational Complexity	Increase Data Quality	Increase User Productivity	Reduce operating cost	Maximize resource value
Company 1	centralized	centralized	centralized	centralized	hybrid	centralized	↑	◑	◕	◕	●	●
Company 2	centralized	centralized	centralized	decentralized	decentralized	decentralized	↑	◕	●	◕	◕	◑
Company 3	centralized	centralized	hybrid	hybrid	hybrid	hybrid	↑	◕	◕	◕	◕	◕
Company 4	centralized	decentralized	hybrid	decentralized	decentralized	decentralized	↑	◕	◕	◕	◕	○
Company 5	centralized	hybrid	hybrid	hybrid	centralized	hybrid	↑	◑	◕	◕	◕	◕
Company 6	decentralized	decentralized	hybrid	decentralized	decentralized	hybrid	↑	◑	◕	◑	◑	◑
Company 7	hybrid	centralized	decentralized	decentralized	hybrid	decentralized	↑	◕	●	◕	●	◑
Company 8	hybrid	hybrid	hybrid	hybrid	hybrid	hybrid	↑	●	◕	●	○	◑
Company 9	centralized	centralized	centralized	centralized	centralized	hybrid	→	◕	◕	◕	◑	◑
Company 10	centralized	centralized	centralized	centralized	decentralized	hybrid	→	○	◑	◑	◑	◑
Company 11	centralized	centralized	centralized	hybrid	centralized	hybrid	→	◕	◕	◕	◕	◕
Company 12	centralized	centralized	hybrid	hybrid	centralized	hybrid	→	◕	◑	◑	◕	◕
Company 13	centralized	decentralized	hybrid	hybrid	hybrid	hybrid	→	◕	◕	◕	◕	◕
Company 14	decentralized	decentralized	decentralized	decentralized	decentralized	decentralized	→	○	◑	○	○	○
Company 15	hybrid	hybrid	centralized	decentralized	hybrid	hybrid	→	◑	◕	◕	○	◕
Company 16	not specified	centralized	hybrid	hybrid	decentralized	centralized	↓	◑	◑	◑	◑	◑

Key

Data Confidence
- ↑ High
- → Moderate
- ↓ Low

Benefits Realized
- ● Achieved
- ◕ Partially achieved
- ◑ Expected within 2 years
- ○ Unable to achieve
- ○ Not a priority
- Included in business case

Table 5: RIM Data Entry Summary

We have been tracking RIM connection points since our first RIM study in 2013, and although there have been many plans to connect RIM to other key functional systems such as eTMF, QMS, and label artwork management, the connections have always been only aspirational—until 2024. But now we are finally seeing progress on connectivity not only between *systems* but, more strategically, between *functions* by means of the use of data aggregation platforms (e.g., data lakes and data warehouses) and enterprise capabilities such as master data management (MDM) and reference data management. Figure 14 reviews that progress from 2020 through 2024. If we add in the will-implement-this-year data and the will-implement-in-2025-or-2026 data, we find the top three future RIM connections to be QMSs, at 63% of participants; data aggregation platforms, at 60% of participants, with the highest percentages being large and midtier companies; and MDM systems, at 53% of participants.

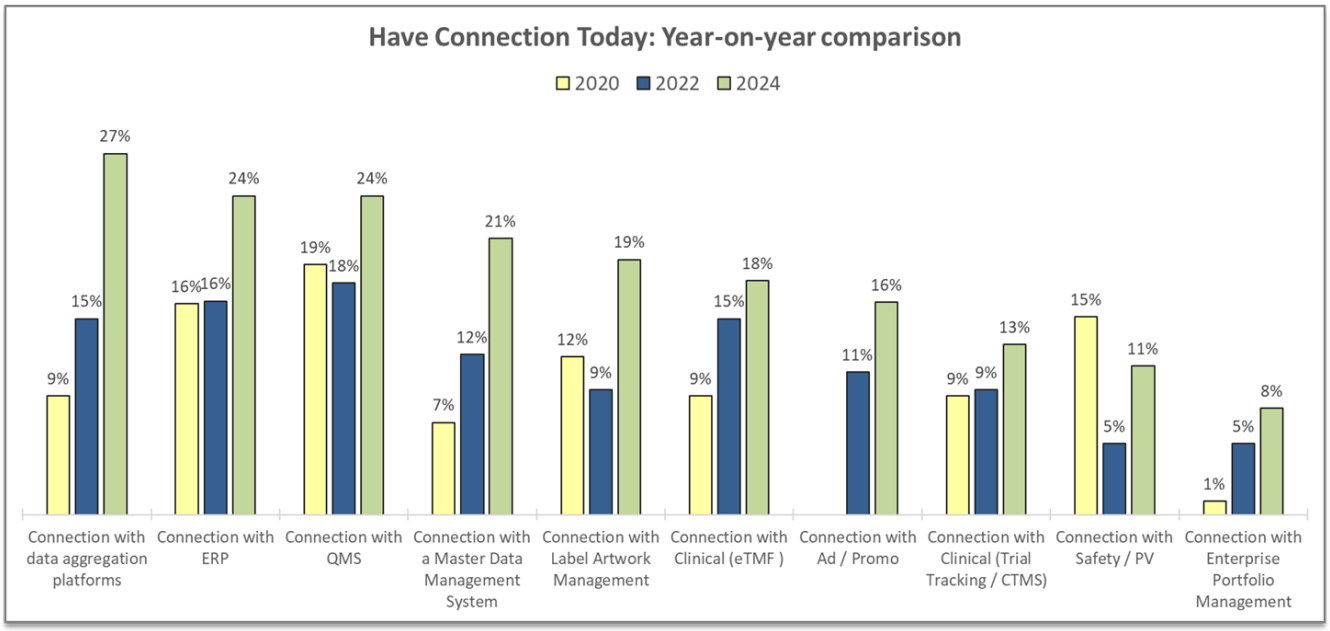


Figure 14: RIM Connection Progress

Advanced-Technology Maturity and Investment Priorities

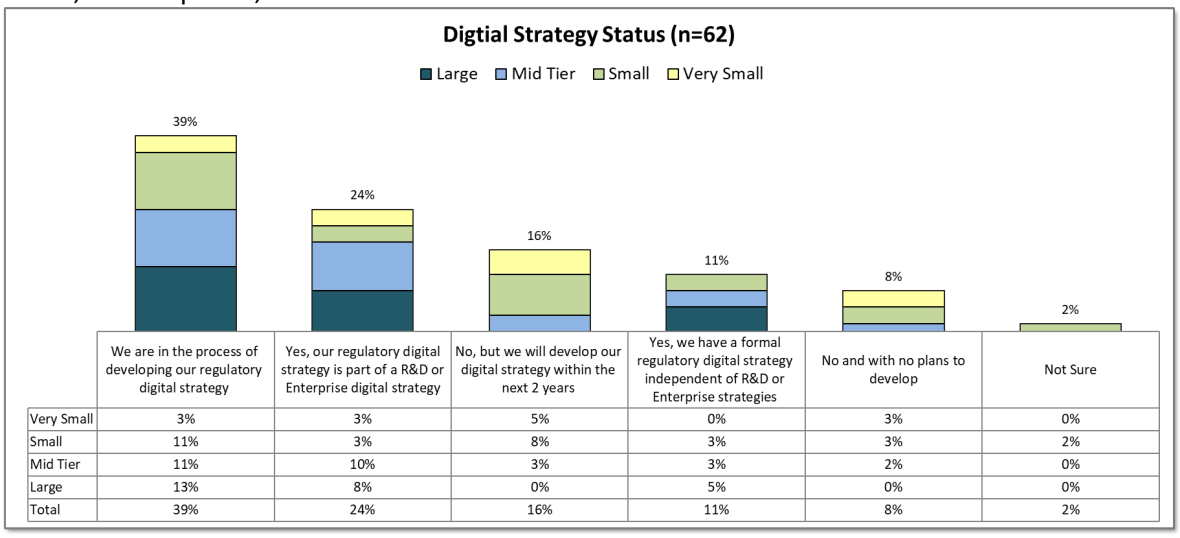
The 2024 World Class RIM research continues exploring the use of advanced technology in regulatory as part of the effort to reduce manual work, improve efficiency, and maximize the benefits of RIM capabilities. By means of this research, we continued the evolution of the ways we approach the use of technology to manage regulatory information. In previous research cycles, we were interested primarily in whether a company had or didn't have an authoritative source for its regulatory information and what kinds of systems were used for managing the information.

Fast-forward to 2024, and virtually all companies have a global authoritative source or sources and are using centrally managed, commercial systems. We also observe that most companies are increasing their explorations of common sets of advanced automation or artificial intelligence projects within regulatory. For example, the automation use cases we've tested for several survey cycles are being planned or investigated by most companies, although the level of implementation is still relatively low.

Digital Strategy Maturity Status

What has become increasingly interesting is the maturity of the processes, organization, data quality, and systems that support the management of regulatory information. Therefore, in this survey, we focused on digital strategy maturity, investments, and lessons learned. The first question was, Do you have a formal digital strategy for regulatory information? (Figure 15).

Ninety percent of responding companies said they have, are developing, or are planning a formal digital strategy, with 35% indicating a strategy is in place today. We also learned that a few companies (11%) have a strategy dedicated to regulatory—one that is independent of a broader enterprise digital strategy, which, in our opinion, is a tactical mistake.



	We are in the process of developing our regulatory digital strategy	Yes, our regulatory digital strategy is part of a R&D or Enterprise digital strategy	No, but we will develop our digital strategy within the next 2 years	Yes, we have a formal regulatory digital strategy independent of R&D or Enterprise strategies	No and with no plans to develop	Not Sure
Very Small	3%	3%	5%	0%	3%	0%
Small	11%	3%	8%	3%	3%	2%
Mid Tier	11%	10%	3%	3%	2%	0%
Large	13%	8%	0%	5%	0%	0%
Total	39%	24%	16%	11%	8%	2%

Figure 15: Digital Strategy Status

We were also interested in the maturity of that strategy. We used our digital strategy framework developed in March 2013 and reviewed by 44 companies in our fall 2023 survey design sessions to evaluate a company's digital strategy maturity. That framework (Figure 16) is closely aligned with the Gens & Associates performance pyramid (Figure 6) and was developed due to the 2023 hype of advanced technology promise in the short-term, or follow-the-shining-object syndrome, with the shiny

object being technology and not the foundational elements of data assets, skills, and measurements to support and evaluate the advanced technology.

We used that framework to evaluate a company's digital strategy maturity in the forms of:

- Organization and culture
- Process and analytics
- Technology assets
- Data assets

We were not surprised to find that most companies rate themselves as maturing in all four elements (Figure 17). A few companies evaluate themselves as mature in one or two elements. Only two companies (one large and one midtier, both of which are in our top performer cohort) said they are fully mature in all four elements.

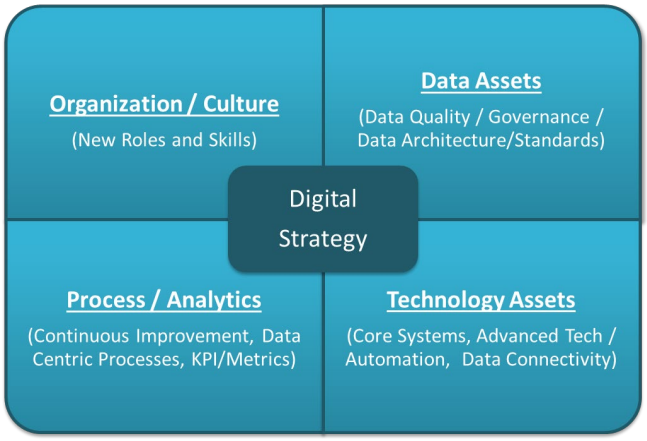
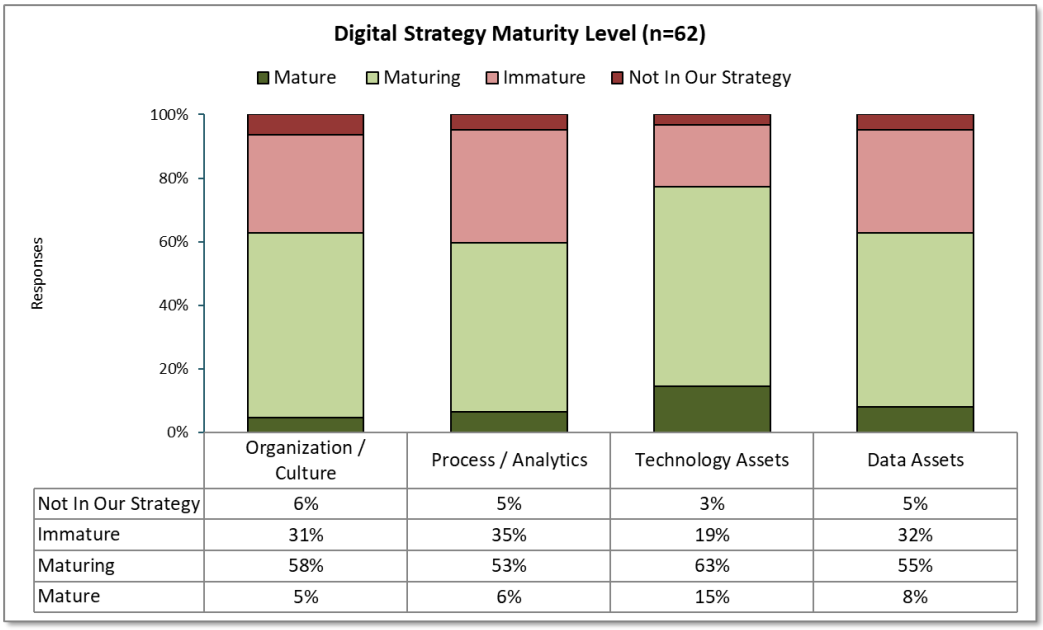


Figure 16: Digital Strategy Framework



	Organization / Culture	Process / Analytics	Technology Assets	Data Assets
Not In Our Strategy	6%	5%	3%	5%
Immature	31%	35%	19%	32%
Maturing	58%	53%	63%	55%
Mature	5%	6%	15%	8%

Figure 17: Digital Strategy Maturity

We believe mature components (e.g., data quality, defined roles and responsibilities, and metrics for continuous improvement) are important for all four elements in the model so as to successfully implement automation and fully achieve the benefits of that automation in regulatory.

Technology Investment

In 2024, we asked two questions about investment in various technology categories. The first question asked for estimated investment with regard to level of effort in nine technologies—such as MDM, GenAI, data aggregation platforms, and structured content authoring.

We defined effort as a combination of funding and staff/contractor time. Companies were asked to indicate whether their level of effort was significant, moderate, or low—based on an individual company's own criteria for significant, moderate, or low. Figure 18 shows the percentage of companies that indicated either significant or moderate investment in the next two years. The graph also shows responses for an almost identical list of technologies in the 2022 research.

The three technology areas with the highest investment effort in 2024 are MDM, GenAI, and data aggregation platforms (e.g., data hub, data lake, data warehouse, and Microsoft Fabric). More than half of the surveyed companies identified those three platforms as either significant or moderate investments.

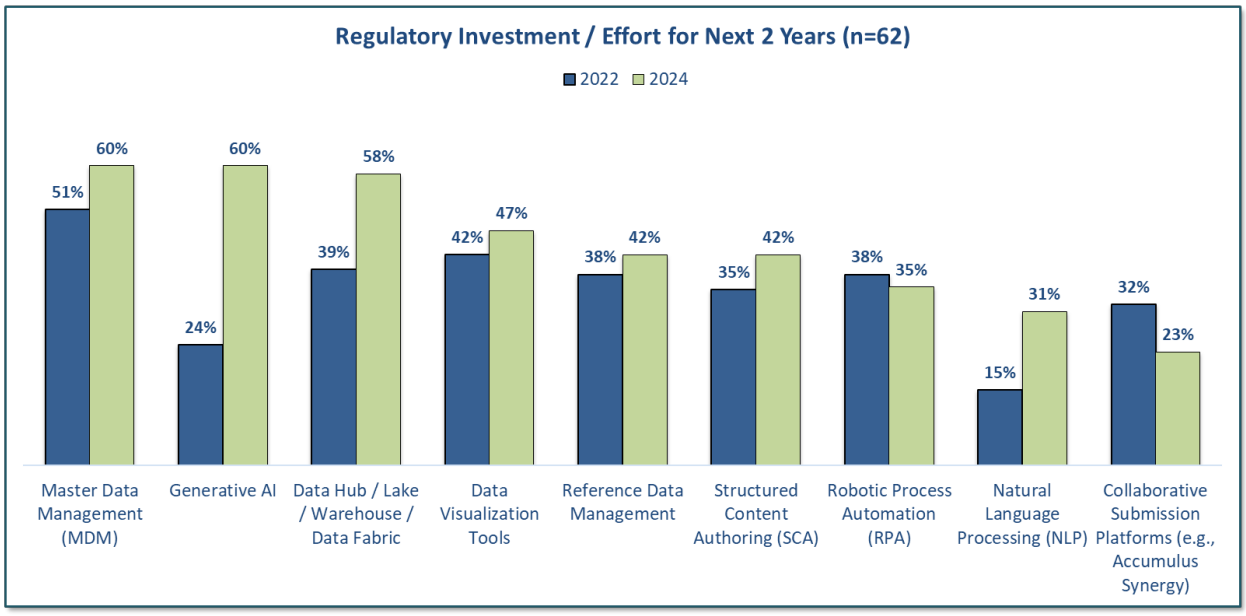


Figure 18: Technology Investment in Terms of Effort

Among large companies, more than half of the large companies identified all nine technology areas as having significant or moderate investments. Compared with 2022's responses, the investment level in every technology area, except two, increased in 2024. The two areas that were lower in 2024 were robotic process automation (38% → 35%) and collaborative submission platforms (32% → 23%).

The second investment question asked companies to estimate expected funding in 2024 and 2025 of five specific technologies by using a series of US dollar ranges. About one-third of participating companies provided responses, so we view the data and results as directional and not authoritative for informing budgets or decision-making.

Figure 19 shows average funding and number of responses for the combined large and midtier cohort. Figure 20 shows results for the combined small and very small cohort.

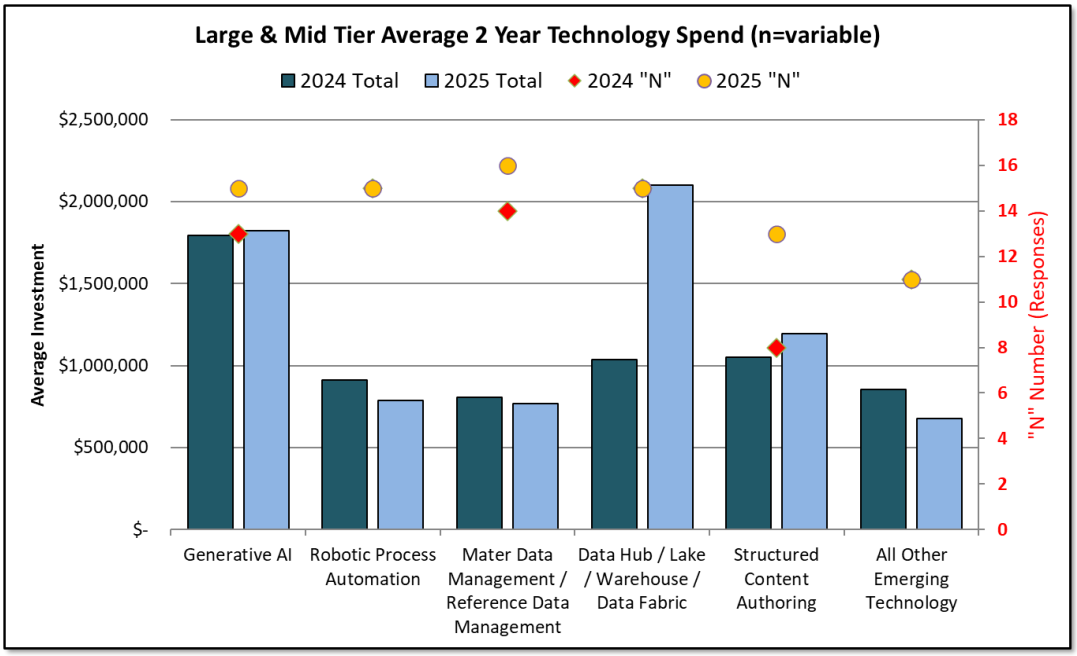


Figure 19: Large and Midtier Estimated Technology Spend

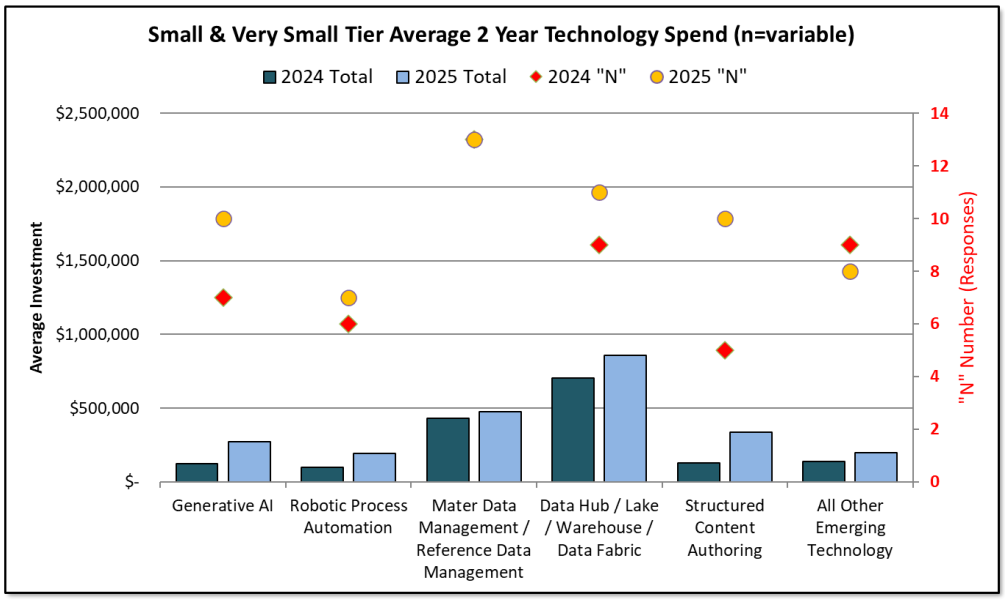


Figure 20: Small and Very Small Company Estimated Technology Spend

Some of the results we found interesting are as follows:

- Large and midtier companies average a spend of close to $1 million per year across most technology categories, with the highest being GenAI spend and averaging more than $1.5 million per year.
- For large and midtier companies, data aggregation platform average spend is $1 million in 2024 and increases to an average of $2 million in 2025.

- Finally, the average spend by small companies is less than $500,000 per year and in some cases, much less than $500,000 (e.g., spend on GenAI).

Lessons Learned from Proof-of-Concept Experience

We asked companies that conducted an advanced automation proof of concept and that decided *not* to proceed to full development to share the challenges they encountered and any lessons learned from the experience. Seventeen companies provided narrative descriptions of their experiences.

We classified the comments into nine areas, of which the following five areas are the most significant:

1. **Technical and Data Quality Limitations**
   - *Challenges:* Companies faced technical limitations of the tools used and insufficient data quality, which resulted in extensive manual rework due to unreliable data sources.
   - *Learnings:* A thorough understanding of the data and the technical limitations early in the process is important, as is prioritization of data quality so as to maximize the effectiveness of automation technologies.
2. **Business Process Complexity and Uncertain Return on Investment**
   - *Challenges:* Companies faced the uncertainty of adequate return on investment for certain advanced technologies. Companies were also challenged by complex and nonrepeatable business processes, as well as difficulty in justifying the cost of such projects.
   - *Learnings:* Companies must prioritize high-volume activities to justify expenses and streamline business processes, with a view to make them more amenable to automation.
3. **Regulatory and Compliance Issues,** which companies reported in addition to process challenges
   - *Challenges:* Companies encountered challenges when their automation solution interacted with good-practice-compliant systems. In such situations, it became more difficult to gain acceptance from a regulatory perspective and to ensure compliance with IT security requirements.
   - *Learnings:* Companies must address regulatory and compliance issues early in the process and collaborate closely with IT security groups.
4. **Issues with Solution Providers**
   - *Challenges:* Companies believe vendors are overpromising the capabilities of their solutions. And implementation costs tend to be higher than expected, which may be due to several factors such as data and process issues within the companies themselves as well as the vendor solution shortfall.
   - *Learnings:* Companies must conduct thorough vendor assessments, must manage expectations realistically, and must ensure that the technology they use aligns with their organizational needs.
5. **Organizational Readiness and Commitment**
   - *Challenges:* Companies questioned their management's lack of understanding, management's insufficient commitment to transformative approaches, and organizational resistance to change.

- *Learnings:* Project owners must get buy-in from management and ensure organizational readiness for technological transformation.

In summary, many of such projects' encountered challenges align with lack of maturity in the elements of the digital strategy discussed earlier in this section—especially with regard to the need for clearly defined and globally adopted regulatory processes and data that is available and of high quality.

We see the addressing of those areas as important parts of the path to effective automation of regulatory processes.

Software Provider Landscape Summary

The software provider landscape has gone through a major transition driven by technology advancements, industry requirements, and economic factors. We estimate the spending for the top 500 during the past five-year period was $3.8 billion driven primarily by RIM modernization. The market dynamic is changing, with the maturing of several E2E RIM provider platforms that continue to shrink the available market for niche providers.

Since we introduced the concept of an E2E RIM approach in 2016, we have been closely tracking both provider software strategy positioning and industry system strategy preference (platform versus a simplified, best of breed). Regardless of system strategy option, though, the clear direction is simplification at both the process and system layers. Our 2024 data (Figure 21) shows that 55% have an E2E strategy, with another 27% in a likely-to-adopt status. Our definition of E2E strategy is the adoption of a single platform for most of our 15 RIM capabilities, with the exceptions of publishing, label compliance, and regulatory intelligence.

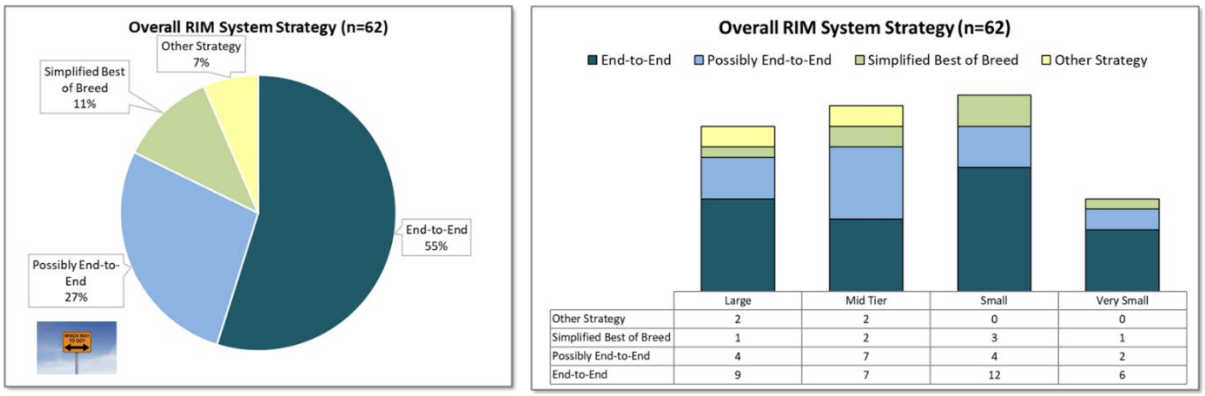


Figure 21: RIM System Strategy

We view the market through three categories of software providers (Table 6) today. We realize that not all providers can be reviewed in this section, and the omission of a provider does not signal either a positive, neutral, or negative interpretation by the research team. That is particularly true for providers that serve the medical device community, because our design history file sample size is small.

Platform
ArisGlobal / Amplexor
Ennov
Generis
IQVIA
Rimsys (medtech only)
RegDesk (medtech only)
Veeva

Platform (emerging)
Extedo (via the Generis platform)
Fryer Solutions (emerging)
LORENZ

Best of Breed Connected
DXC Technology
OpenText/Documentum

Table 6: Software Provider Categories

Platform providers. This cohort has most of the 15 core RIM capabilities in their platforms. Although most claim to have robust publishing and label compliance tracking capabilities, we believe they are still maturing those capabilities. Most providers in this cohort do not have a regulatory intelligence solution to date, except for IQVIA and RegDesk, both of which do have mature regulatory intelligence capabilities.

Emerging platform providers. This cohort has a traditional best-of-breed base in either the content or data side of RIM and is in the process of expanding their solution to encompass most RIM capabilities.

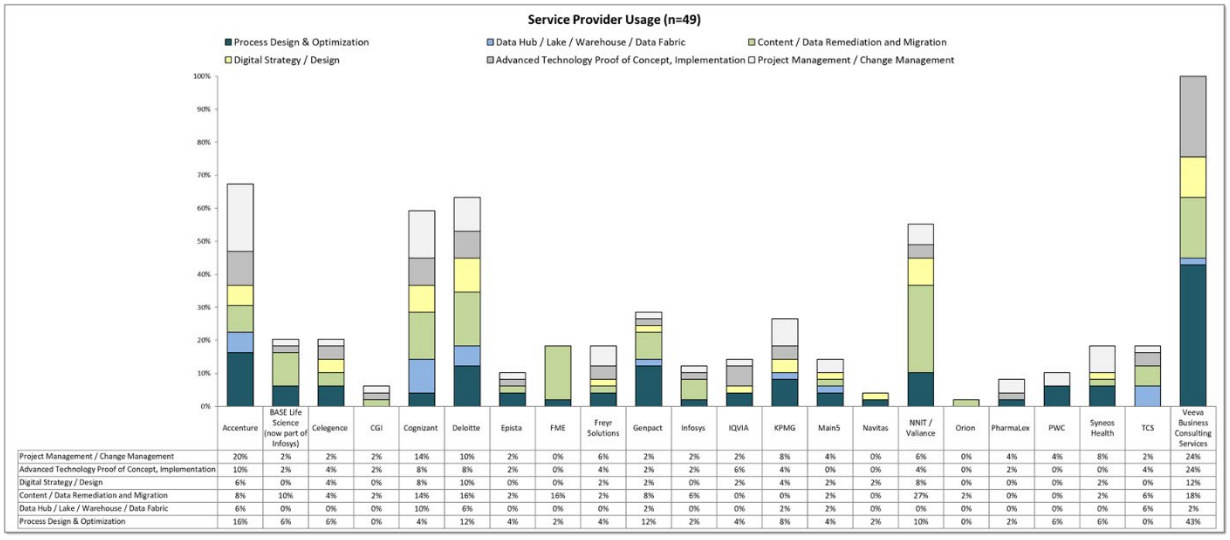
Best-of-breed connected. This cohort has strengths in a much smaller subset of what we consider E2E RIM, and most have been affected by E2E RIM adoption.

Table 7 depicts 2024's market share summary. (Our market reports contain very detailed data about market share, customer satisfaction levels, and innovation perceptions.) Compared with 2022, we see Veeva gaining a considerable share in the product registration and label compliance tracking area and LORENZ retaining market leadership for publishing in all tiers. The table's boldface entries depict providers that have increased their market leadership and share for each solution type within a market tier since 2022.

Solution Type	Large Tier (n = 16)	Mid Tier (n = 19)	Small / Very Small Tier (n = 26)
Submission Content Management	1) Veeva 2) OpenText – Documentum 3) Generis	1) Veeva 2) OpenText -Documentum 3) SharePoint	1) Veeva **2) Box**, DXC , OpenText – Documentum
Publishing	1) LORENZ 2) Calyx / DXC Technology / **Veeva**	1) LORENZ 2) Calyx 3) Veeva / **DXC**	1) LORENZ **2) DXC / Extedo / Veeva**
Product Registration	1) Veeva 2) Calyx	1) Veeva **2) Calyx** / Custom	1) Veeva 2) ArisGlobal
Label Tracking	**1) Veeva** 2) Custom 3) Intagras	1) Veeva 2) Custom **3) i4i**	**1) Veeva** 2) Custom **3) ArisGlobal**

Table 7: Summary of Market Leaders by Size of Company (May 2024)

We have been tracking key software implementation partners for six years and decided to expand our tracking to include providers that assist in the areas of digital strategy, advanced-technology proofs of concept, and data aggregation platform implementation (Figure 22). The overwhelming majority of those providers continue to be rated as having an "overall positive experience" by industry.



	Accenture	BASE Life Science (now part of Infosys)	Celegence	CGI	Cognizant	Deloitte	Epista	FME	Fryer Solutions	Genpact	Infosys	IQVIA	KPMG	MainS	Navitas	NNIT / Valliance	Orion	PharmaLex	PWC	Syneos Health	TCS	Veeva Business Consulting Services
Project Management / Change Management	20%	2%	2%	2%	14%	10%	2%	0%	6%	2%	2%	2%	8%	4%	0%	6%	0%	4%	4%	8%	2%	24%
Advanced Technology Proof of Concept, Implementation	10%	2%	4%	2%	8%	8%	2%	0%	4%	2%	2%	6%	4%	0%	0%	4%	0%	2%	0%	0%	4%	24%
Digital Strategy / Design	6%	0%	4%	0%	8%	10%	0%	0%	2%	2%	0%	2%	4%	2%	2%	8%	0%	0%	0%	2%	0%	12%
Content / Data Remediation and Migration	8%	10%	4%	2%	14%	16%	2%	16%	2%	8%	6%	0%	0%	2%	0%	27%	2%	0%	0%	2%	6%	18%
Data Hub / Lake / Warehouse / Data Fabric	6%	0%	0%	0%	10%	6%	0%	0%	0%	2%	0%	0%	2%	2%	0%	0%	0%	0%	0%	0%	6%	2%
Process Design & Optimization	16%	6%	6%	0%	4%	12%	4%	2%	4%	12%	2%	4%	8%	4%	2%	10%	0%	2%	6%	6%	0%	43%

Figure 22: Software Implementation Partner Summary

Our software and service market reports contain additional details as well as total-addressable-market data for readers interested in market size and trending.

In past white papers, several pages had analysis notes containing our opinions on each of the software providers we track. Those in the Gens & Associates membership have access to our market reports and our subject matter experts to discuss any specific software provider in detail. We embraced podcasting in 2023, and in summer 2024, we started a regulatory executive series with eight software providers' holding one-on-one conversations with Managing Partner Steve Gens on the future direction of their organizations and product road maps. At the time of publication of this paper, the episodes were as follows:

1. ArisGlobal (Chief Customer Officer)
2. Extedo (CEO)
3. Fryer Solutions (Cofounder and co-CEO)
4. Generis (CEO)
5. LORENZ (CEO)
6. RegDesk (Founder and CEO)
7. Rimsys (Founder and CEO)
8. Veeva (Head of Regulatory System Strategy)

The podcasts can be accessed from our Knowledge to Share web page at https://gens-associates.com/gens-associates-podcast/.

Study Conclusion

We wish to offer you several last themes as you make progress on your organization's journey or your clients' RIM performance journeys.

- The tipping point has tipped, and survey data shows substantial increases in operating performance across all dimensions of the World Class RIM rating categories, including average efficiency for 15 RIM capabilities, metrics program characteristics, data quality levels, time to report information, and affiliate use of global systems.
- There is a clear path to the achievement of high performance, and it starts with excellence in the foundational layer of the RIM performance pyramid in the form of intentional and consistent application of organizational strategies and practices such as data governance, data quality sustainability, and continuous improvement. Plus, a strategic KPI program coupled with global process maturity will directly and positively affect your organization's ability to use technologies and tools to maximize business benefits achievement.
- Advanced technology shows promise, but it has to have reliable data, the right skills, and performance measures to fully realize the opportunities it offers. The current use cases being applied in regulatory are more tactical in nature and should result in positive operational efficiencies. We strongly believe that the development of a digital strategy across an enterprise to mature all of the components of a digital environment (i.e., organization and culture, data assets, process and analytics, and technology assets) represents a strong and comprehensive approach.
- Finally, there will always be opportunities for improvement and there will always be challenges to overcome. Currently, we see complex challenges of (1) optimization of global affiliate networks (improving affiliate engagement is key), (2) data ownership and end-user accountability (clarity and transparency can help), and (3)adoption of data standards that are hindered by uncertainty and the slow pace of change at the health authority level.

Authors

Steve Gens MSOD is a survey cofounder, with the first industry survey having been conducted in 2007. The 2024 World Class RIM will be the 45th survey conducted under Steve's leadership. Steve has more than 35 years of business experience, with the majority of it in the biopharmaceutical and healthcare industries. His early career was at Johnson & Johnson, after which he moved into consulting by managing several healthcare consulting practices for Booz Allen Hamilton and First Consulting Group.

Steve has deep and wide-ranging experience in the areas of strategy formulation and implementation, organizational development and performance, industry benchmarking, information management strategy, and facilitation of strategic change. He consults all sizes of life sciences companies—especially those that are growing and scaling.

Steve has a Master of Science in Organization Development from American University, with distinction for his fieldwork, and a Bachelor of Science in business computer science from Lock Haven University of Pennsylvania. He is a frequent speaker at conferences and workshops and was named to the 2017 PharmaVoice 100 entrepreneur category for his contributions to industry.

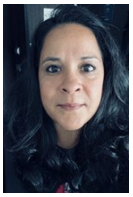
Kelly Hnat BA of K2 Consulting—a survey team member since 2019—has more than 25 years' experience in the pharmaceutical industry, leading both IT and RIM/regulatory operations organizations at several companies, including Wyeth, Pfizer, Shire, and Teva.

Kelly is a key industry leader in the European Union's implementation of IDMP as a member of the SPOR Task Force and its PMS subteam and is a member of ISO TC/215. She is president of IRISS (www.iriss-forum.org) and is on the leadership

Greg Brolund MS has served on the Gens & Associates survey team since 2009. He is a global pharmaceutical management and technology consultant with extensive experience in business processes and support of IT for product labeling, in submission publishing, in global health authority interactions, and in pharmacovigilance programs.

Greg served as rapporteur of the International Council for Harmonisation's M2 Working Group Rapporteur from 1998 through 2002, developing the initial production version of the eCTD and overseeing implementation of the E2B Individual Case Safety Report electronic submission. He has 25 years of experience with the US Food and Drug Administration (FDA), leading development of the agency's internal IT systems in support of the submission review processes of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.

After the FDA, he served as US Department of Health and Human Services chief technology officer and was a pharmaceutical industry consultant with Booz Allen Hamilton. Greg has a Master of Science in chemistry from American University in Washington, D.C., and a Bachelor of Science in chemistry from the University of Massachusetts Amherst.



Preeya Beczek MS - a survey team member since 2023 has 25 years' experience across the life sciences industry. She has led regulatory projects across the entire product lifecycle in various therapeutic areas and platforms. Preeya has held roles at PAREXEL, GSK, Pfizer, JNJ, Ipsen, DOW Chemicals and worked with many other organisations as part of her client base/professional network. She has extensive

team of IRISS's IDMP Topic Group. Her company, K2 Consulting (www.k2rim.com), is a specialty firm focused on regulatory affairs and is a partner of Gens & Associates. Kelly has a Bachelor of Arts summa cum laude in political science from Temple University.

Katherine Yang-Iott MSOD is a core member of the Gens & Associates team, who has more than 20 years of experience in the healthcare and pharmaceutical industries, leading and managing complex interdisciplinary projects.

Katherine was a research scientist at Regeneron Pharmaceuticals and Children's Hospital of Philadelphia before transitioning to consulting to focus on strategy development and continuous-improvement projects in support of research operations. Katherine has a Master of Science in Organizational Dynamics from the University of Pennsylvania and a Bachelor of Science in biochemistry from Virginia Tech.

industry experience and insights to lead and support teams across regulatory functions, in order to meet objectives. She has undertaken many large strategic and operational projects to help organisations reach operational effectiveness and increase regulatory compliance. (e.g., labelling alignment between core and local versions, critical phase submission management, inspection preparation/readiness for EMA and MHRA, standardisation of global submission management processes; designing and establishing risk management and governance frameworks; building the full RA and cross functional infrastructure for first MAH product). Preeya is an excellent facilitator and a 'critical friend', working with clients and cross functional teams operationally and as a subject matter expert. She is passionate about creating effective teams, processes, toolkits and operating models for RA teams to enable global collaboration, data quality and compliance. Preeya holds a Bachelor of Science degree in Chemistry and Management Studies and a Master of Science in Environmental Strategy from the University of Surrey, UK. She is also a qualified Lean Six Sigma Green Belt.

Appendix

15 RIM Categories

1. Submission Forecasting and Regulatory Resource Planning
2. Dossier Management (content plan, distribution, archive)
3. Submission Document Management
4. Submission Production (assemble, publish, quality control, dispatch)
5. Submission Planning and Tracking (short term)
6. Product Registration Management
7. Health Authority Commitment Management
8. Health Authority Interactions (Q&A, correspondence)
9. Regulatory Submission Archive
10. Label Management (content control and compliance tracking)
11. Reporting, Analytics, Dashboard
12. Data Standards and Governance Management
13. Design History File: Medical Device
14. Regulatory Intelligence
15. Advertising and Promotions

14 Connection Points

1. Clinical (eTMF)
2. Clinical Trial Tracking (clinical trial management systems)
3. Enterprise Resource Planning
4. Quality Management Systems
5. Safety and Pharmacovigilance
6. Label Artwork Management
7. Enterprise Portfolio Management
8. Product Life Cycle Management (typically, medical devices)
9. Advertising and Promotions
10. Master Data Management
11. Data Aggregation Platform (pooling from multiple systems, data lakes, etc.)
12. Reference Data Management
13. Medical Information Call Center
14. Customer Relationship Management

Providers in Innovation Rating (sorted alphabetically)

1. ArisGlobal/Amplexor
2. Calyx (acquired by Ennov)
3. DocShifter (acquired by Ennov)
4. DXC Technology
5. Ennov
6. EXTEDO
7. Freyr Solutions
8. Generis
9. i4i
10. Intagras
11. IQVIA
12. Kivo
13. LORENZ
14. OpenText/Documentum
15. Phlexglobal (discontinued software line)
16. RegDesk
17. Rimsys
18. Veeva

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