2022 World Class Regulatory Information Management Study White Paper

Fall Edition: Based on our *2022 World Class RIM℠: Accelerating Business Value* Study (n = 76)

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GENS & ASSOCIATES

Introduction

Our biennial World Class Regulatory Information Management (RIM) study focused this cycle on understanding how industry is accelerating business value, on the status of the regulatory modernization cycle, and on answering the question, What's next for tactical and strategic investments? The past decade has seen significant investment in global RIM programs, with new roles, new processes, and new technologies. And even though the overall industry performance average continues to increase, we still believe there are significant performance opportunities and associated business benefits to realize—in our humble opinion.

This paper highlights key learnings from the 2022 study including our 16 top performers: those achieving strong performance or world class levels. The paper reviews current industry status, key trends, investment priorities, structured data submission program strategy and presents a comprehensive update on the software and service provider landscape. Following are key study takeaways:

- We are witnessing the tail end of the RIM modernization cycle, with organizational evolution, advanced-technology usage, and cross-functional information exchange being what's next.
- We are detecting an increased need for a clear regulatory digitization strategy in partnership with R&D and the enterprise in order to maximize regulatory advanced-technology initiatives.
- We are seeing significant focus and deep desire to properly implement data quality practices and cross-functional data governance strategies that will facilitate efficient information sharing.
- RIM system strategy has evolved to a preferred, end-to-end (E2E) platform approach by 75% of the study's participating organizations, with many software providers solution maturing.
- Our top performers continue to excel in their process and organizational work so as to facilitate technology investments regardless of software provider or system strategy.

The information and graphs herein are based on the 2022 World Class RIM study, COVID-19 Regulatory Impact study results, client work, and our insights. The paper's structure is as follows.

- Demographics and Survey Introduction
- Industry Performance Status and Investment Priorities
- Evolving Organization Strategies and Priorities
- Data Quality Confidence Status and Evolving Data Governance Practices
- Evolving Structured Data Submissions Strategy and Practices
- Advanced-Technology Status and Investment Priorities
- Regulatory Provider Landscape: Key Trends and Performance Status

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


Steve Gens
Founder


Greg Brolund
Since 2009


Sarah Powell
Since 2016


Kelly Hnat
Since 2019


Katherine Yang-Iott
Since 2020

Survey Demographics and Design Strategy

This is our sixth large RIM study since 2013, and it benefits from a continued increase in participant diversity. The respondents represent large, mid-tier, small, and very small organizations (figure 1). Those categories were determined by revenue size through *Pharmaceutical Executive*'s annual Top 50 Companies list and survey demographics. Growing the diversity of companies that have product portfolios such as device, consumer, and agricultural is important to our research. We also had a sizable increase in the number of very small companies (those with zero to three products on the market), because such companies are investing heavily in RIM to properly build and scale their regulatory organizations. We analyzed the data to uncover unique insights and trends by company size, top performers, product type, and geographic area.

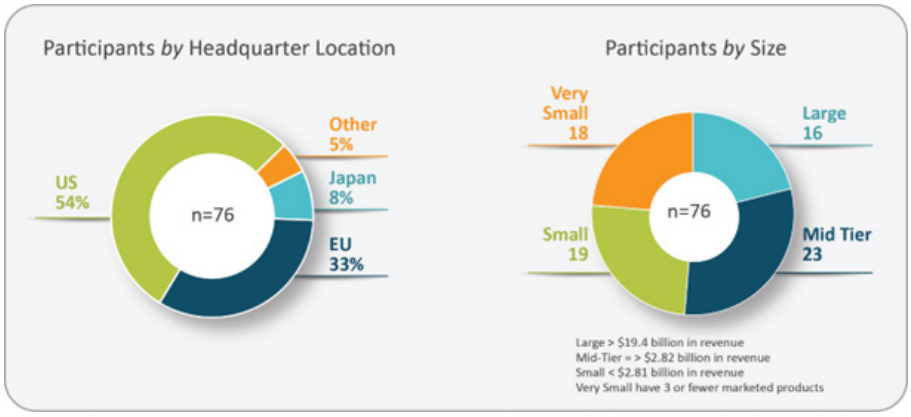


Figure 1: 2022 Survey Demographics

Another key demographic is product portfolio, on which we performed various analyses based on product type and number of products. Figure 2 depicts the product mix of the 76 participating companies.

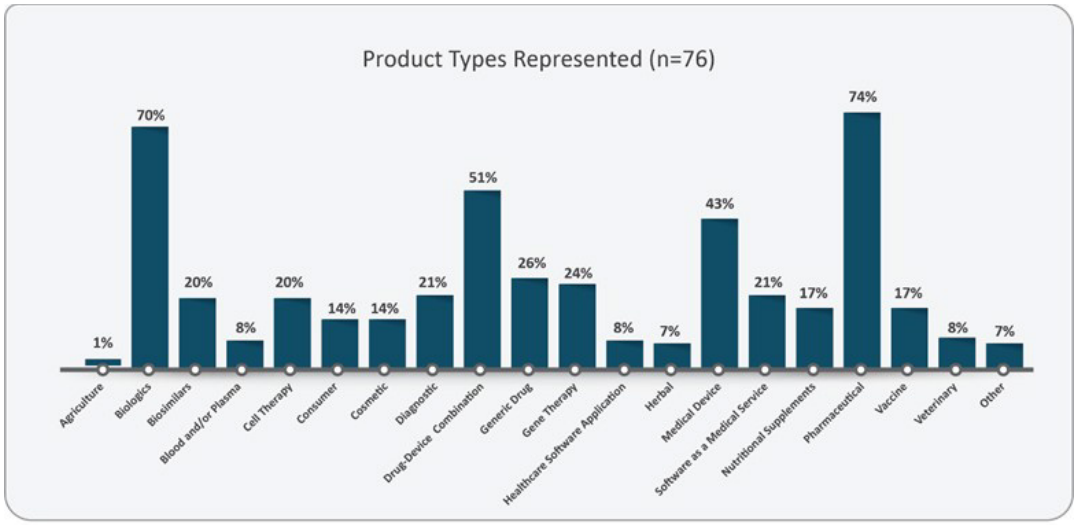


Figure 2: 2022 Product Type Demographic

We appreciate the 45 organizations and our study advisers (figure 3) that contributed to strengthening the survey design in fall 2021. They consisted of 35 companies representing industries that participated in five global design sessions and 10 prominent regulatory software and service providers that participated in two virtual sessions. We greatly appreciated the services of NNIT, which hosted our only in-person design session in Copenhagen; the session had eight regional sponsors, all of which participated in a full-day review and enjoyed a well-needed dinner the night before. In total, 82 individuals participated in our survey design process.

Figure 3: 2022 Survey Contributors

Regulatory Priority Investment Status

Industry continues to invest heavily in strategic regulatory initiatives and E2E cross-functional processes while the historic investment rate in the 15 RIM capabilities continues to drop as most organizations approach completion of their RIM modernization investments—hence our conclusion that we are witnessing the tail end of the regulatory modernization cycle (figure 4).

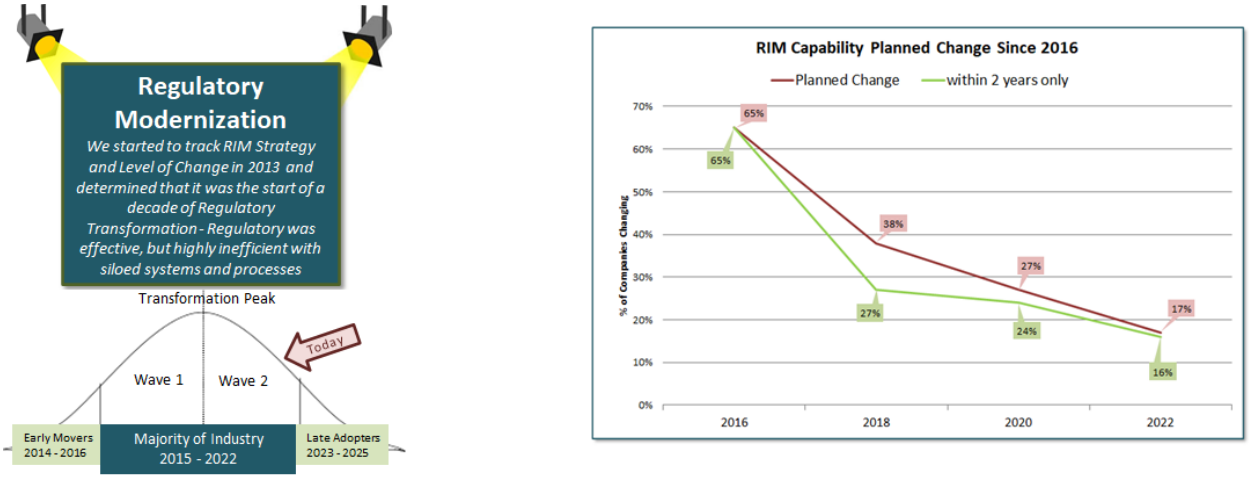


Figure 4: RIM Modernization Cycle (2014–25)

Figure 5 depicts priority RIM-capability near-term investments, E2E process-focused near-term investments, and strategic-initiative-focused near-term investments by tier. A key theme regardless of company size is improved data quality, simplification of the system/process layer, access to real-time information, and health authority focus (e.g., data submissions, commitments, correspondence management).

Dimension	Large (n = 16)	Mid-Tier (n = 23)	Small (n = 19)	Very Small (n = 18)
Top 2 RIM Capability Investments	1) Dossier Management (56%) 2) Regulatory Intelligence (50%)	1) Submission Plan & Track + Dossier Management (both 61%)	1) Reporting / Analytics (74%) 2) Registration Management + Submission Forecasting (both 47%)	1) Submission Plan & Track + Health Authority Commitment Management (both 44%)
Top 2 E2E Process Focus	1) Data Submissions (69%) 2) Health Authority Commitments / Correspondences + Safety Submission (both 44%)	1) Data Submissions (83%) 2) Regulatory Intelligence + CTA (both 48%)	1) Data Submissions (47%) 2) New Label – CCDS (47%)	1) CTA (56%) 2) CMC Change Control + Regulatory Intelligence – Country Filing Requirements (both 44%)
Top 3 Strategic Initiative Focus	1) Improve Data Quality + Strategic Data Management (both 88%) 2) Continuous Improvement + e-Labeling (both 94%) 3) RIM System / Process Simplifications (81%)	1) RIM System / Process Simplifications (96%) 2) Improve Data Quality + Data Governance (both 76%)	1) Improve Data Quality (84%) 2) RIM System / Process Simplifications (74%) 3) Global RIM Adoption + Real Time Dashboards (both 68%)	1) RIM System / Process Simplifications (56%) 2) Improve Data Quality + Real Time Dashboards (both 50%)

Figure 5: Investment Priority by Tier Analysis

Among all study participants, 32% have completed global RIM adoption, and 54% are actively working to achieve that critical business goal. Overall RIM capability efficiency (average of the 15 RIM capabilities) has moved from 48% to 56%, with ad/promo and submission productions having the highest efficiency ratings (90% and 89%, respectively); reporting /analytics and submission forecasting and resource planning had the lowest ratings (36% and 33%, respectively).

Figure 6 depicts business benefit realization (fully and partially achieved) of 16 business benefits we track in the study. Boldface items signify business benefits that are consistent across market tiers.

Dimension	Large (n = 16)	Mid-Tier (n = 23)	Small (n = 19)	Very Small (n = 18)
Highest Business Benefits (Fully and Partially Achieved)	**1) Increase data quality of authoritative sources (75%)** **2) Access to real-time information (88%)** 3) Better integration of business processes (69%) 4) Improve information exchange with other functions (69%) 5) Simplify local affiliate interactions (69%)	1) Improve outcomes of an audit or HA inspection (65%) 2) Speed to respond or react to a regulation change (61%) 3) Reduce operational complexity (57%) **4) Access to real-time information (52%)** 5) Improve the quality / consistency of HA interactions (52%) **6) Increase data quality of authoritative sources (43%)**	**1) Access to real-time information (58%)** 2) Reduce operational complexity (47%) 3) Improve outcomes of an audit or HA inspection (47%) **4) Increase data quality of authoritative sources (42%)** 5) Better submission planning and forecasting (42%)	1) Reduce operational complexity (56%) **2) Access to real-time information (44%)** **3) Increase data quality of authoritative sources (44%)** 4) Better integration of business processes (44%) 5) Improve the quality / consistency of HA interactions (44%)

Figure 6: Business Benefit Realization Summary

World Class RIM Performance Status

We created the World Class RIM performance model with 35 companies from 2015 to 2017. For 2022, we expanded slightly the number of key performance indicators and increased the efficiency weighting to the 15 RIM capabilities.

Figure 7: World Class RIM Categories

World Class RIM: 5 Elements, 11 Questions

The following describes the core five World Class RIM categories (figure 7) 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 (46):** This category comprises 14 business benefit realization statuses, 21 key performance metric usages (out of a possible 33), continuous improvement program status, and operating cost understanding.
3. **Global Reach: Global System Deployment Status (7):** *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 (19):** 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 to data-quality confidence levels. We ask nine common regulatory questions; for example, what products are registered in what countries? 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 8 depicts the placement of the 76 participants and their relationships to their tier averages, the strong-performance band, and the World Class level. Two companies achieved World Class, and 14 are in the strong-performance band. Regarding our study title, "Accelerating Business Value," there was improved performance by the mid-tier-company and large-company performance averages (orange line below) compared with the 2020 study.

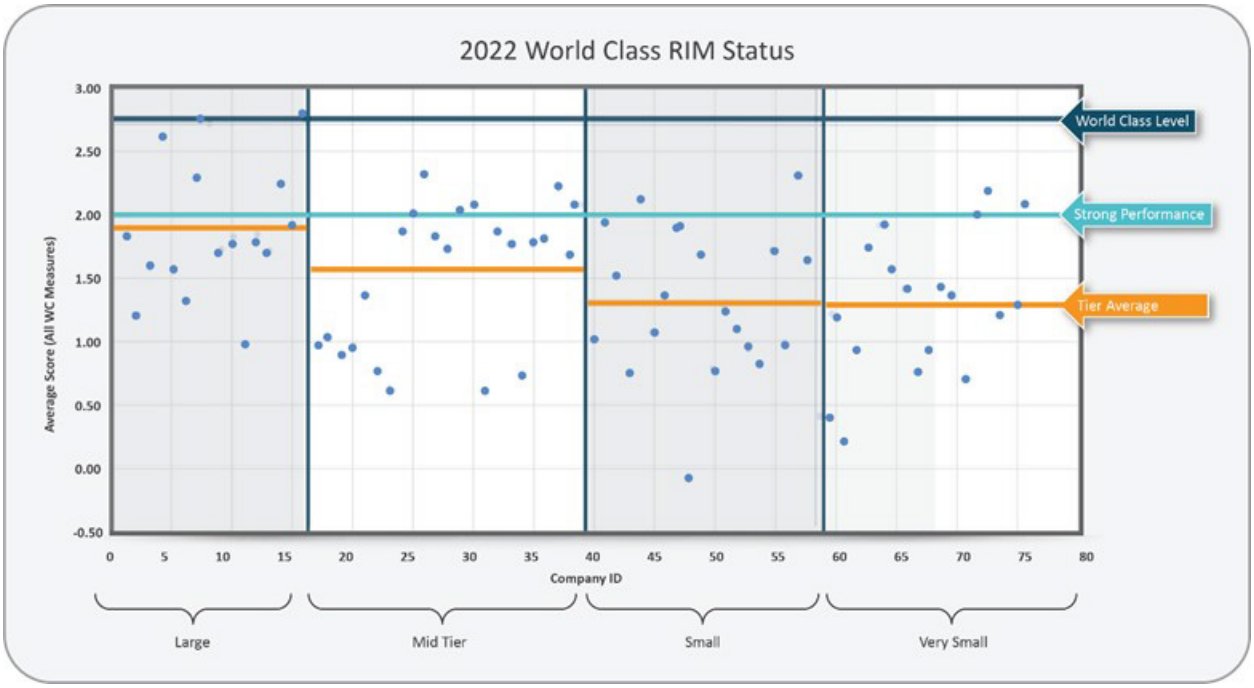


Figure 8: World Class RIM Benchmark Results

We see the group of top performers as a predictor of future industry performance, and figure 9 depicts seven key dimensions, or indicators, of top-performing organizations. The gap between the tier average level and the strong-performance level has narrowed for the large and mid-tier companies, and the small-tier and very-small- tier companies have remained at the same performance levels. The overall message of that comparison is, "what is possible" for the everyone-else cohort!

Dimension	Top Performers (n = 16)	Everyone Else (n = 60)
15 RIM Capability (see appendix for listing) Efficiency Average	79%	49%
16 Business Benefits Achieved (fully + partial)	82%	33%
Global RIM System Adoption (7 systems)	76%	50%
Data Quality Confidence (11 information categories)	66%	30%
RIM Connection Point Maturity (11 connection Points)	39%/61%	22%/78%
Organization Characteristics (culture, agile, innovation, advocacy, implementation success etc.)	84%	58%
RIM System Strategy "most likely + likely" (E2E vs Simplified Best of Breed)	69%/56%	75%/39%

Figure 9: Top Performers vs Everyone Else Performance Comparison

Shifting Organization Priorities

In 2020, we introduced our RIM Performance Framework (figure 10), which models how the combination of strong foundational organizational elements and process maturity levels helps drive performance and value from chosen RIM investments to achieve and maximize business benefits. The basis of our opinion for the path to high performance is rooted in research with more than 120 companies in our World Class RIM benchmark and 15 years of regulatory consulting projects. Based on this year's research, we continue to see no correlation between the study's top performers and any one regulatory solution provider *or* system strategy (platform versus simplified best of breed). The data have been consistent since 2014, which reemphasizes that RIM high performance is not achieved solely by investment in a particular tool or by partnering with a specific software provider; instead, performance improvement happens through intentional and focused work on the organizational and process levels to fully leverage technology investments.

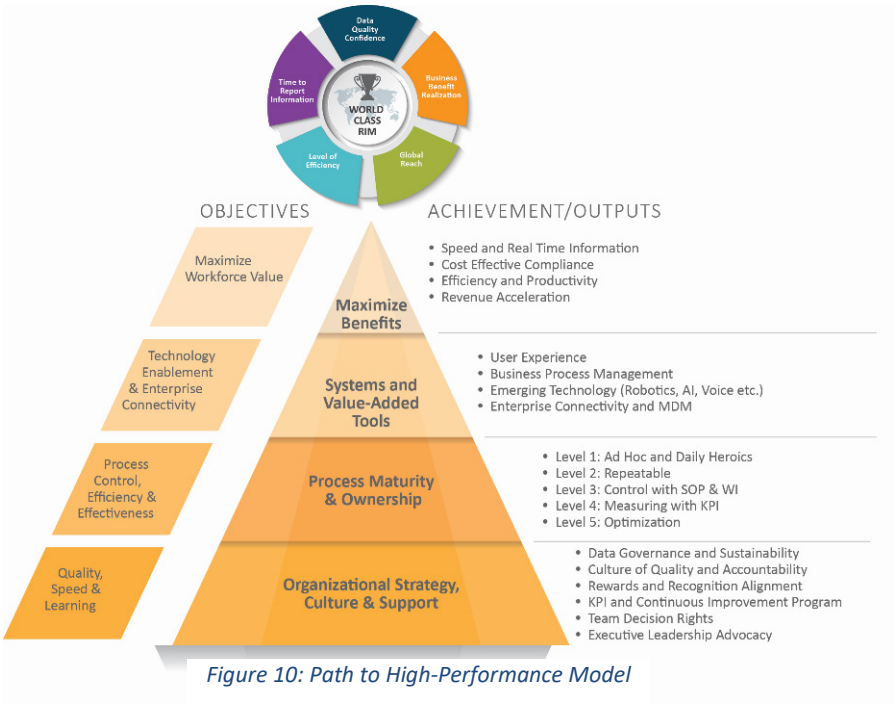


Figure 10: Path to High-Performance Model

There are several paths to high performance; some companies get there through brute force by means of daily heroics; others manage in a so-called better way. Additional key learnings through conversations with last year's top-performing companies attributed the achievement of world class performance levels to company culture and critical organizational elements such as leadership advocacy and decision rights. With those two points in mind, we developed a new section for this year's study so as to benchmark and explore possibilities and concepts of that so-called better way. We asked companies about different organizational strategies and cultural elements (figure 11) to become able to better understand the impact or role that strategies could have on optimizing overall performance. We learned that culture makes a difference and that a systematic approach to evolving mindsets, workforce, process work, and thinking about the future of the organization results in a series of improvements. Company culture is such a critical success factor because it sets the tone of the organization and strongly influences how people get work done. If efficiency, quality, and innovation are high on a company's list of priorities—as they should be—then consider the cultural work to be establishing a practical approach that will foster the type of environment that leads to the company's success.

In our survey, we evaluated a dozen different statements about organizational culture and practices. Some statements are more character oriented than others and best represent how companies see themselves (i.e., strong, collaborative cultures; quality mindsets; aspirations to become industry leaders), which we view as aspirational characteristics. Other statements speak to efforts made to embody those characteristics, and they are more action oriented (i.e., quick to react, effective execution of plans, known decision-making processes). The key to strengthening performance improvement lies in a combination of organizational beliefs and organizational efforts.

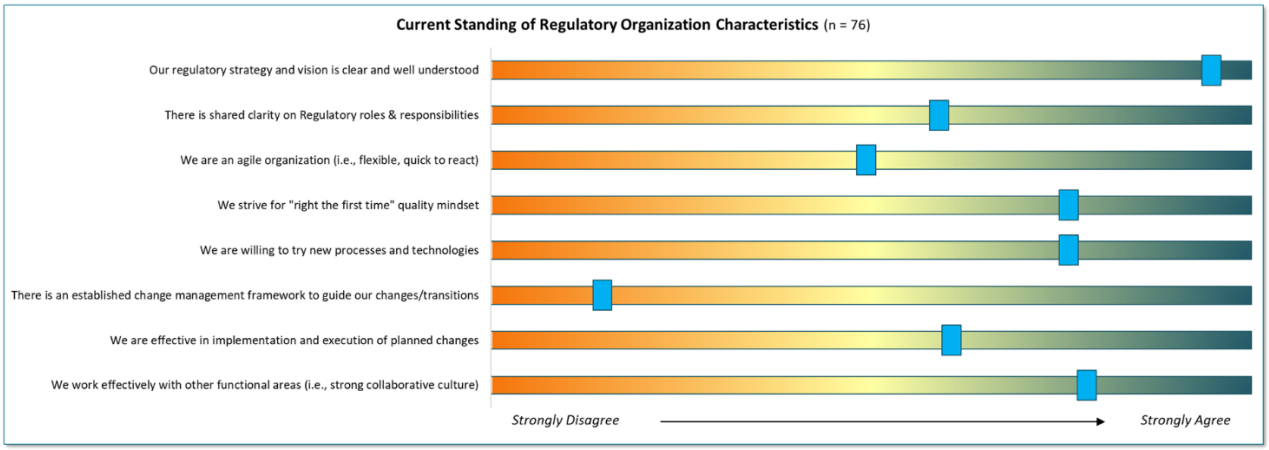


Figure 11: Organizational-Characteristics Summary

We scored a subset of the statements, widely accepted to positively affect dynamics within organizations, shown in figure 11, which represents the current standings of regulatory organizations (n = 76). Although most companies say they have a clear and well-understood regulatory vision and strategy, we see opportunities to improve many other areas, including clarification of roles and responsibilities, organizational agility, project implementation, and transition management. Very few companies have established change-management frameworks, which we believe falls into the category of the better way to manage an evolving regulatory organization—especially given the amount of work and change indicated in the study and because skilled change agents need time for development and experience if they are to achieve optimal outcomes.

As we dug deeper into the data, we saw that the cohort of 16 top performers are indeed more systematic in their approaches to organizational strategy. The alignment between their beliefs and their actions is closer than that in other organizations that have high aspirations (their beliefs) but have yet to ground those aspirations with practicality (their actions). Top performers scored higher in all of the organizational statements we tested (figure 12).

Fully 100% of the top performers (n = 16) said they:

- Have a clear and well-understood regulatory strategy and vision
- Are willing to try new processes and technologies
- Strive for a right-the-first-time quality mindset

- Are effective in the implementation and execution of planned changes

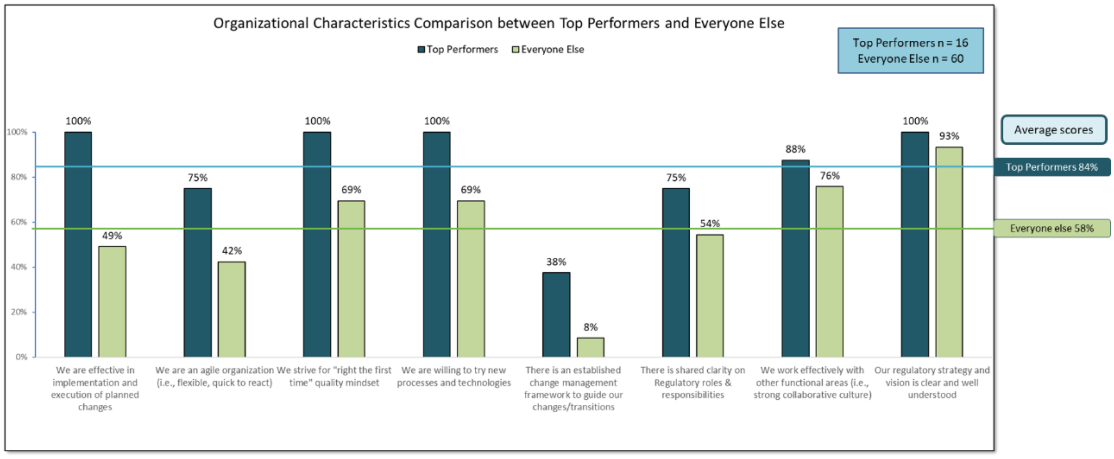
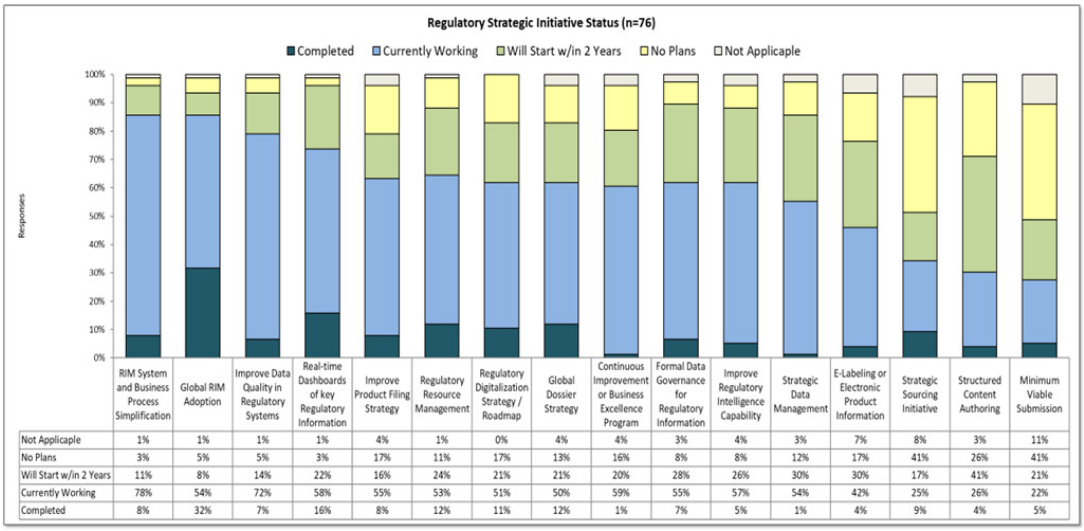


Figure 12: Top Performer versus Everyone Else Organizational Characteristics

In 2018, we started to see an increase in end-to-end process work among many cross-functional business processes. Currently, many companies either (1) are in the midst of working on processes such as data submissions (61%) and clinical trial application processes (42%) or (2) recently completed E2E process work in the forms of health authority commitment and correspondence management (50%); chemistry, manufacturing, and controls (CMC) change (47%); and submission of safety data (47%). We also see a lot of current-work status for many of the regulatory strategic initiatives (figure 13) we tested, in which most of the initiatives are multiyear projects that focus on better structuring of data in order to increase speed, efficiency, and compliance (i.e., RIM system and business process simplification (78%), global RIM adoption (54%), and data quality improvement (72%). Those changes and initiatives will progress as we near the end of the decade-long modernization cycle and as companies strive toward better performance and maximizing of business benefits, which leads to another shift in priorities as organizations evolve their workforces.



	RIM System and Business Process Simplification	Global RIM Adoption	Improve Data Quality in Regulatory Systems	Real-time Dashboards of key Regulatory Information	Improve Product Filing Strategy	Regulatory Resource Management	Regulatory Digitalization Strategy / Roadmap	Global Dossier Strategy	Continuous Improvement or Business Excellence Program	Formal Data Governance for Regulatory Information	Improve Regulatory Intelligence Capability	Strategic Data Management	E-Labeling or Electronic Product Information	Strategic Sourcing Initiative	Structured Content Authoring	Minimum Viable Submission
Not Applicaple	1%	1%	1%	1%	4%	1%	0%	4%	4%	3%	4%	3%	7%	8%	3%	11%
No Plans	3%	5%	5%	3%	17%	11%	17%	13%	16%	8%	8%	12%	17%	41%	26%	41%
Will Start w/in 2 Years	11%	8%	14%	22%	16%	24%	21%	21%	20%	28%	26%	30%	30%	17%	41%	21%
Currently Working	78%	54%	72%	58%	55%	53%	51%	50%	59%	55%	57%	54%	42%	25%	26%	22%
Completed	8%	32%	7%	16%	8%	12%	11%	12%	1%	7%	5%	1%	4%	9%	4%	5%

Figure 13: Regulatory Strategic Initiatives Status

For each section of the survey, when we looked at the trending data, we kept asking, "What's next?" Evolving the regulatory workforce to align with the future of work is a big part of "what's next," and it is something we clearly see in our consulting work. In the past 18 months, we've seen increases in activity, energy, and thinking by companies exploring and investing in ways to inject innovation into the regulatory organization by upskilling their regulatory workforces; by redefining and clarifying roles and responsibilities; and by introducing emerging roles to align with strategic initiatives and longer-term goals. In the survey, we find that companies have significant interest in data governance roles in the next two years (45%), along with data analysts (20%) and data architects (23%) too, which aligns with the ongoing work we see with regulatory teams' plans to improve data quality confidence. Large-tier companies and top performers are ahead of the curve, with many of these roles already active today. On the flipside, the growing conversations about digitalization efforts do not align with related roles, because less than 50% of companies have active digitalization leads (38%), regulatory intelligence automation analyst (23%), agile roles (35%), or data governance roles (38%), which leads us to question whether and why some companies are stuck in the aspirational phase when it comes to their digitalization goals.

We believe it is highly beneficial for leaders to consider what their regulatory organization will look like in five years, because roles and responsibilities *will change* with system and process changes; that work is being done now. As capabilities mature and as systems connect and as technology advances, there will be a shift in the ways people "do" the work to the ways people "manage" how work gets done; and new skills like creativity, strategizing, decision making, and innovation will be required to support the business going forward. Emerging core competencies will center on proficiency in technologies, end-to-end process thinking, and collaboration. Performance and business goals such as accelerating business value realization, aligning on a digitalization strategy, and data quality sustainability can best be accomplished through an evolved workforce with the right skill sets. Bottom line is that *people* are required in order to get work done, and as the work itself evolves, so should the workforce.

The path to high performance should consist of defined intentions, efforts, and alignment between people, processes, and tools in an optimized environment. There may be many ways to achieve high performance, but our RIM performance framework can guide toward the so-called better way. And remember that culture makes a difference; organizations may not be able to see it, but everyone can feel it.

Data Quality Confidence Status and Evolving Data Governance Practices

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

Industry continues to struggle with quality of data from designated authoritative sources, as seen in figure 14; and when we look at the responses across all categories, we see an aggregate high-confidence score of only 38%, which is only slightly higher than the 2020 aggregate score of 33%. Less than half of respondents report high confidence in most of the areas we test; the only two categories in which more than 50% of companies report high confidence are regulatory submission archive (54%) and submission document management (53%). It is notable that both of those categories are primarily document focused.

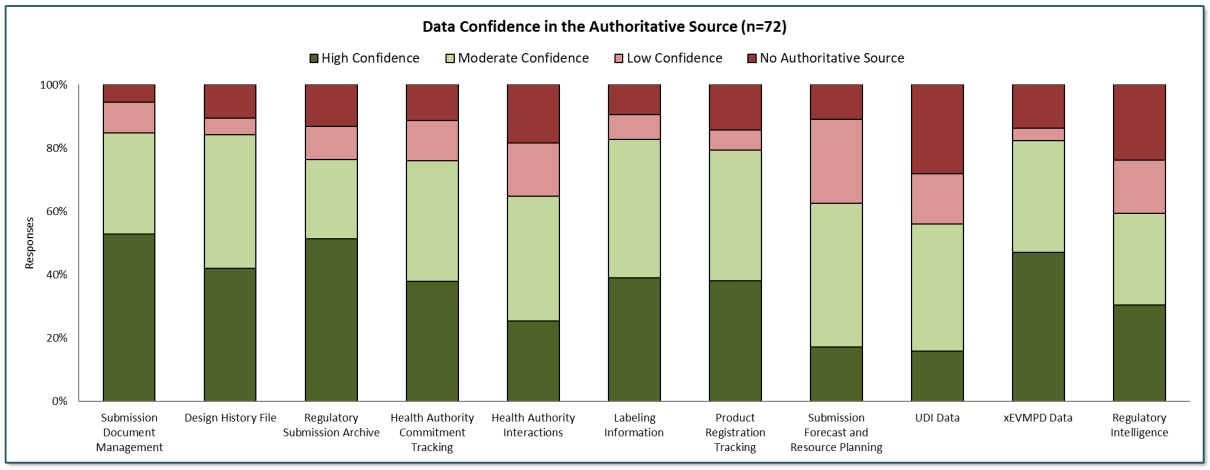


Figure 14: Data Confidence Summary

We believe that data quality sustainability and data governance are critical components for moving the data quality confidence needle forward. We wanted to better understand the state of practices within organizations around data governance and data quality to get a deeper view of what is going on. Leveraging our experience and our data quality sustainability model, we developed two new questions for the 2022 survey that focused on data governance and data quality practices: one that evaluates the status of key data quality and governance practices and one that looks at the involvement of key regulatory authority roles in data-governance-focused activities.

We were not surprised to find that the practices needed for achieving strong governance and data quality are still in early adoption across the industry, and our top performers are quite a bit ahead of the rest. Figure 15 shows eight key data quality practices as a maturity model, comparing the results for our top performers with all other companies. Generally, the top performers are engaged in improving and optimizing existing data quality practices, and the all-others cohort is focused on planning and initial implementation.

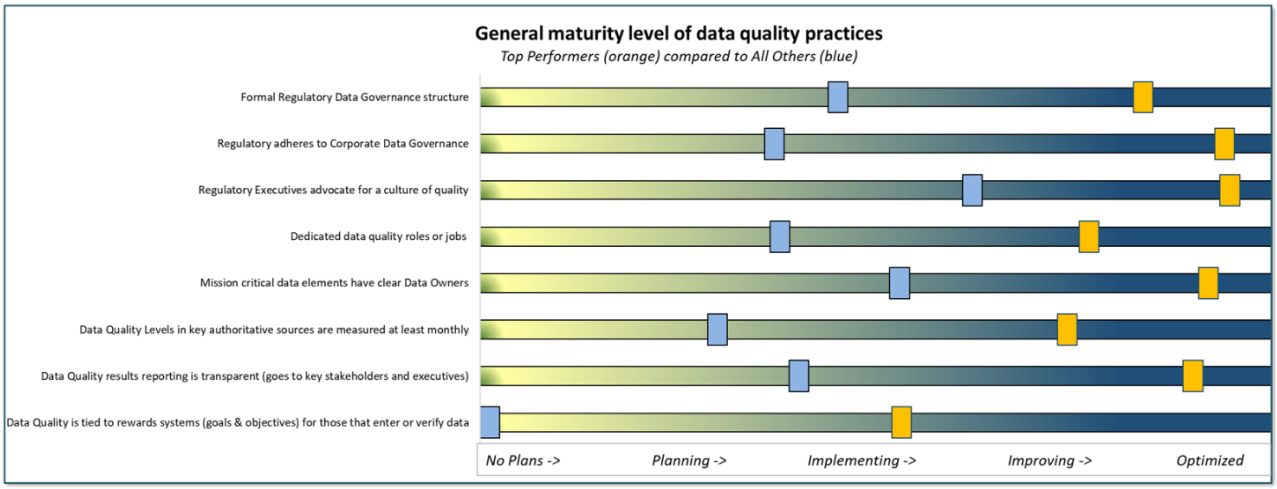


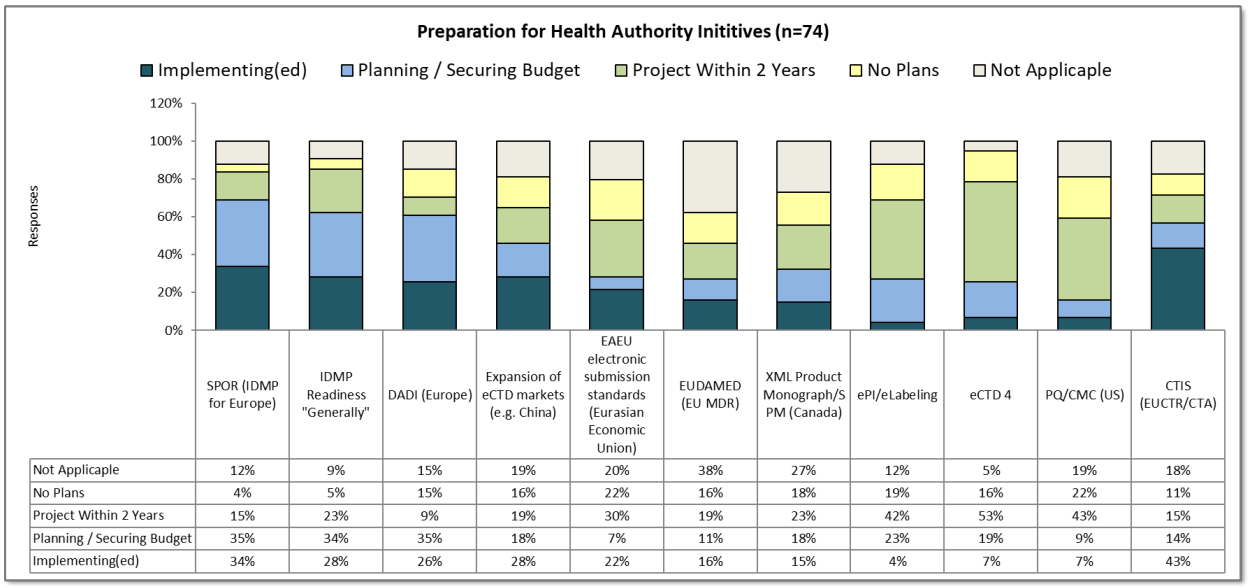
Figure 15: Data Quality Practice Maturity

The two top-performing areas for the all-others cohort are "Regulatory executives advocate for a culture of quality" and "Mission-critical data elements have clear data owners." Those are two important first steps toward establishing data quality sustainability, and we hope to see these organizations expand into some of the more-mature practices in the coming years—especially the two additional practices that are strongest among our top performers: "Regulatory adheres to corporate data governance" and "Transparency of data quality results reporting."

We believe that effective data quality sustainability and data governance programs will prove to be key factors 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 those capabilities. In fact, 55% of all companies reported that they are currently working on formal data governance for regulatory information, and another 28% said they plan to start within two years.

Evolving Structured Data Submission Strategy, Practices, and Connection Points

The past two years have been a whirlwind for industry when it comes to structured data submissions: in 2020, the path was clear for SPOR/IDMP, but this was turned upside down at the end of 2021 by the news that the European Medicines Agency (EMA) will be implementing the Digital Application Dataset Integration (DADI) web portal first and will be delaying Fast Healthcare Interoperability Resources (FHIR) message submission indefinitely. In the meantime, EMA's IRIS portal has come into production; the US FDA continues to tease PQ/CMC and its own IDMP guidance, which has been expected to come at any time for the past couple of years; the Canadian Structured Product Monograph moved into production pilot; and EUDAMED has been slowly coming into being. Figure 16 shows the status of preparation for key heath authority initiatives reported by the 74 companies that participated in the survey.



	SPOR (IDMP for Europe)	IDMP Readiness "Generally"	DADI (Europe)	Expansion of eCTD markets (e.g. China)	EAEU electronic submission standards (Eurasian Economic Union)	EUDAMED (EU MDR)	XML Product Monograph/SPM (Canada)	ePI/eLabeling	eCTD 4	PQ/CMC (US)	CTIS (EUCTR/CTA)
Not Applicaple	12%	9%	15%	19%	20%	38%	27%	12%	5%	19%	18%
No Plans	4%	5%	15%	16%	22%	16%	18%	19%	16%	22%	11%
Project Within 2 Years	15%	23%	9%	19%	30%	19%	23%	42%	53%	43%	15%
Planning / Securing Budget	35%	34%	35%	18%	7%	11%	18%	23%	19%	9%	14%
Implementing(ed)	34%	28%	26%	28%	22%	16%	15%	4%	7%	7%	43%

Figure 16: Structure Data Submission Status

When we began designing the 2022 survey, the IDMP landscape in Europe looked one way—only to change abruptly just as we began design reviews with industry; It therefore necessitated a redesign of the SPOR-related portion of this section. And during the February–March time frame this year, while they were preparing their responses to our survey, participating companies were also still grappling with the shift from FHIR to DADI and awaiting more detail from EMA about exactly what it all meant.

In keeping with the tumult that has shaped the 2022 SPOR/IDMP landscape, we added some questions to our survey in order to learn the impact of these unexpected changes on industry's confidence in the EMA (figure 17) as well as the ability of industry to obtain and retain the budget and cross-functional support required to advance ongoing or pending SPOR/IDMP preparation activities. Fully 53% of all organizations surveyed reported somewhat reduced confidence or significantly reduced confidence in EMA's ability to successfully deliver the Product Management System (PMS), and a withering 71% of organizations reported reduced confidence in any implementation timelines communicated by EMA. Of those organizations that reported no difference in confidence, a few noted that it was their already low confidence that had not changed.

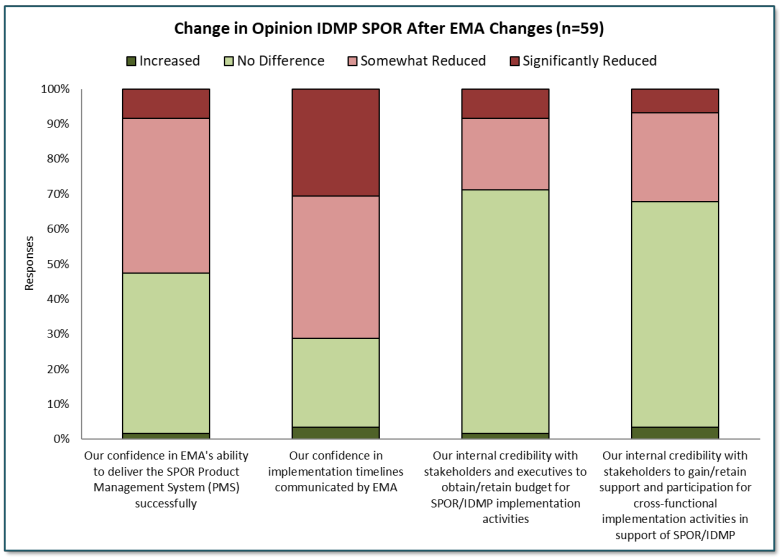


Figure 17: EMA Opinions on Strategy Shift

Internal credibility for SPOR/IDMP initiatives shows a hit, though not as high as we feared: 29% of organizations reported reduced ability to obtain and retain budget, and 32% reported reduced internal support and cross-functional participation in these initiatives. At the time of our survey, 42% of companies said they had not changed their internal implementation plans for SPOR/IDMP, although 24% had paused or delayed their starts pending additional clarity from EMA, and 31% are extending timelines for their existing projects.

With 71% of organizations planning or actively implementing their SPOR/IDMP solutions, we were interested to see what level of automation is planned to pull data from supply chain and other systems and to populate their SPOR/IDMP solutions (figure 18). Few organizations plan full automation of supply chain (19%) or other systems (11%); a much higher proportion plan partial automation (30% and 38%, respectively).

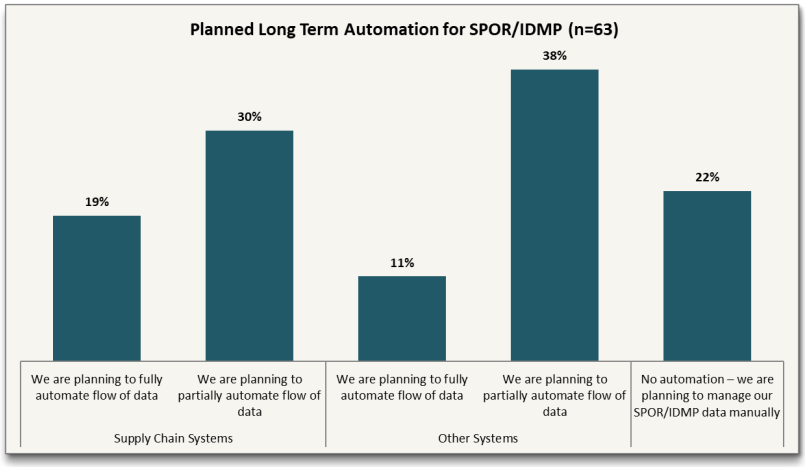
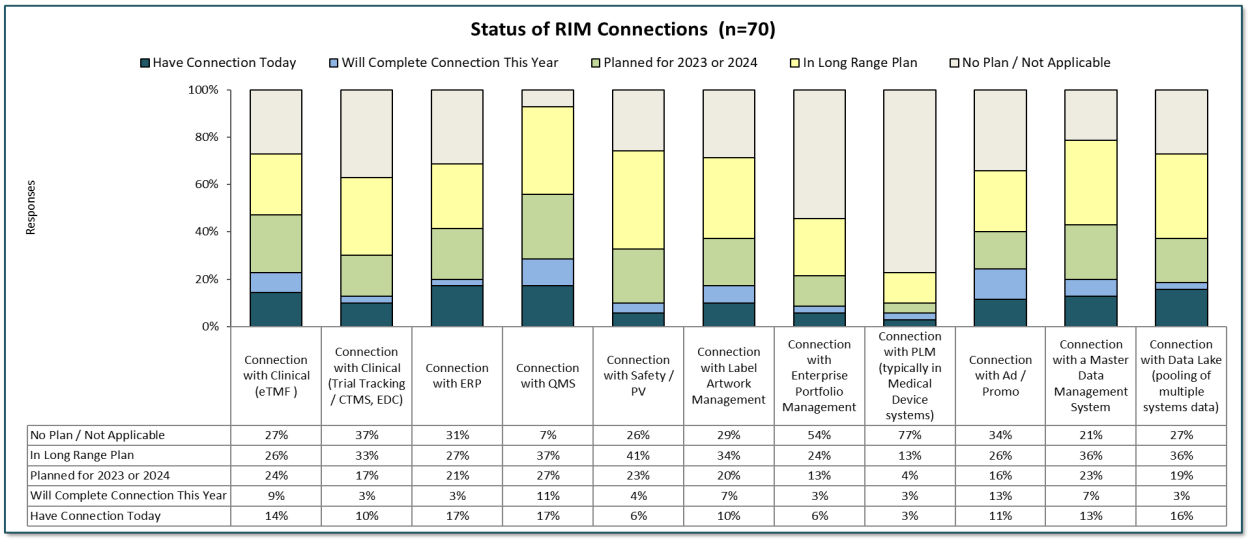


Figure 18: Planned Long-Term Automation Views

The slowness to adopt cross-functional data automation is also evident when we look at RIM connection points (figure 19), which is the connection of RIM capabilities with other systems across the enterprise. The highest scores for connection points in production today are ERP (17%), QMS (17%), data lakes (16%), and clinical/eTMF (14%). A small percentage of organizations plan to complete connections this year. More significant is the number of organizations planning connections in the next two years—particularly for QMS (27%), eTMF (24%), master data management (MDM), (23%), and safety/pharmacovigilance (23%). If these ambitions are realized, it would mark a significant shift in RIM's role in the enterprise.



	Connection with Clinical (eTMF)	Connection with Clinical (Trial Tracking / CTMS, EDC)	Connection with ERP	Connection with QMS	Connection with Safety / PV	Connection with Label Artwork Management	Connection with Enterprise Portfolio Management	Connection with PLM (typically in Medical Device systems)	Connection with Ad / Promo	Connection with a Master Data Management System	Connection with Data Lake (pooling of multiple systems data)
No Plan / Not Applicable	27%	37%	31%	7%	26%	29%	54%	77%	34%	21%	27%
In Long Range Plan	26%	33%	27%	37%	41%	34%	24%	13%	26%	36%	36%
Planned for 2023 or 2024	24%	17%	21%	27%	23%	20%	13%	4%	16%	23%	19%
Will Complete Connection This Year	9%	3%	3%	11%	4%	7%	3%	3%	13%	7%	3%
Have Connection Today	14%	10%	17%	17%	6%	10%	6%	3%	11%	13%	16%

Figure 19: RIM Connection Status

Advanced-Technology Usage and Investment Priorities

The 2022 world class RIM research continues the investigation of regulatory organizations' use of advanced technology as part of the effort to reduce manual work, improve efficiency, and maximize the benefits of RIM capability. We restructured the survey to explore two specific aspects of advanced technology as follows.

- Level of investments in specific emerging-technology areas
- Level of activity and interest in 12 sample regulatory use cases that would use one or more advanced-technology or automation methods

Emerging-Technology Areas

Figure 20 shows technology areas along with percentages of responses that indicated significant investment or moderate investment in each area. The results are shown for all responses and for each

tier defined in the survey (Large, Mid-Tier, Small, and Very Small). The green shading indicates areas with investment by 50% or more of the responses in each tier. The red shading indicates investment by 10% or less of the responses. Note that large companies are investing in many more of the technologies than the other tiers are. It is also noteworthy that foundational and strategic technologies such as master data management, reference data management and data hub/lake/warehouse are among the areas of highest investment. More on this below.

Advanced Technology Area	All Responses (n=74)	Large (n=15)	Mid Tier (n=23)	Small (n=18)	Very Small (n=18)
Master Data Management (MDM)	51%	67%	74%	50%	11%
Data Visualization	42%	60%	61%	33%	11%
Data Hub / Lake / Warehouse	39%	80%	48%	17%	17%
Reference Data Management	38%	67%	61%	11%	11%
Robotic Process Automation (RPA)	38%	73%	48%	22%	11%
Structured Content Authoring (SCA)	35%	73%	39%	17%	17%
Business Intelligence	35%	60%	39%	11%	33%
Collaborative Submission Platforms	32%	67%	30%	22%	17%
AI / Machine Learning Algorithms	24%	73%	26%	6%	0%
Low Code Application Platforms	22%	53%	22%	11%	6%
Knowledge Maps (data relationships / ontologies)	18%	40%	22%	0%	11%
Data Mining	18%	53%	22%	0%	0%
Advanced Search	16%	27%	13%	11%	17%
Natural Language Processing (NLP)	15%	53%	13%	0%	0%
Predictive Analytics Tools	11%	33%	9%	6%	0%
Natural Language Generation (NLG)	8%	27%	9%	0%	0%
Voice Recognition	1%	0%	4%	0%	0%

Figure 20: Technology Investment Level (Significant and Moderate)

Figure 21 shows another view of the technology areas. In this view, we propose a possible alignment of each technology area with an architecture layer.

Foundation

- The foundation layer consists of technology, software, processes, and organizational structures that, as the name implies, support everything else.
- Typically, the foundation elements are enterprise-wide and support cross-functional capabilities such as master data management, reference data management, governance, data management, and data quality roles and processes.

Strategic

- These are capabilities that are built upon and that use the foundation layer to, for example, collect information and make it available from multiple sources. Initially, this may be solely within regulatory, but these capabilities are structured to support cross-functional information sharing.

- Typical implementations are data lakes, data warehouses, and data marts.
- Multiple instances of strategic capabilities are common—often to support specific information-sharing objectives.

Transactional

- These are capabilities that normally depend on the foundational and strategic layers.
- Transactional solutions are typically designed (1) to leverage information beyond the normal capabilities of standard RIM systems and (2) to reduce manual efforts for well-defined, repeatable processes such as robotic process automation.

There is significant current or planned investment in technology in each layer. We believe that the development and implementation of solutions in each layer can be concurrent if an overall digital strategy and architecture encompass all layers. If the architecture is viewed as a jigsaw puzzle, you can add pieces (i.e., technology elements) anywhere in the puzzle. You don't have to start at the bottom or along an edge as long as all the pieces fit together once you're finished.

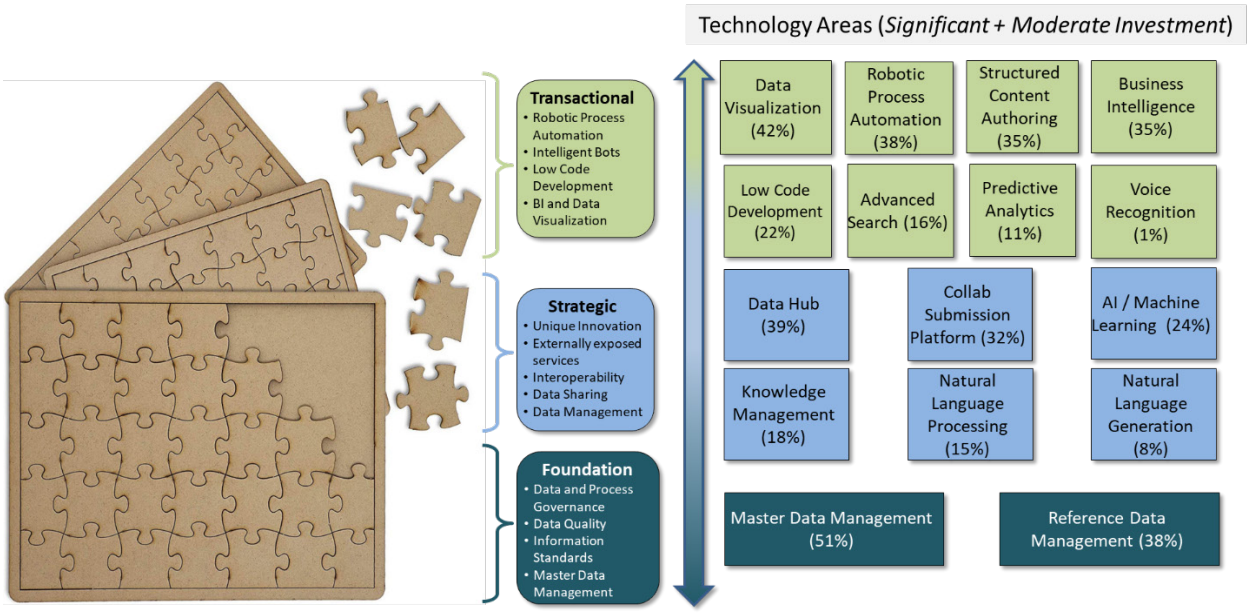


Figure 21: Fitting into a Digitization Strategy

The demonstrated investment across the entire spectrum corresponds to business pressure in each layer that we have observed when working with our clients. There are upward pressures and downward pressures. At the foundation layer, there is pressure from the enterprise to establish the foundation and the strategic elements. Those elements typically require relatively lengthy implementation times and are usually intended to support cross-functional information exchange and aggregation at the enterprise level. There is also pressure from individual functions (e.g., regulatory and regulatory operations) to quickly implement transactional elements in order to provide immediate relief from inefficient or routine manual work. We believe a comprehensive strategy and architecture support cooperative development through all layers of the model to achieve "what's next."

Regulatory Use Cases

Building on our 2020 research into the use of advanced technology in regulatory, we updated the list of regulatory use cases that would most likely require advanced technology for incorporation into a solution that would support the use cases. Most of the use cases aim to improve quality and improve operational efficiency.

The full set of use cases is shown in Figure 22. The percentages shown represent companies, in total, and for each tier that have expressed significant interest in each use case. Significant interest is defined either as (1) in production or implementing or (2) conducting a proof of concept or (3) including the use case in a request for proposal. For example, the top two use cases in terms of significant interest are automating document quality checks and automating document creation.

The tier breakout shows that companies in the large tier generally have the highest level of interest, especially in the use cases shown in green, in which more than 50% of the large companies have significant interest.

Use Cases	All Responses (n=74)	Large (n=15)	Mid Tier (n=23)	Small (n=18)	Very Small (n=18)
Automating document quality checks	46%	80%	39%	28%	44%
Automating document creation	43%	67%	35%	39%	39%
Intelligent search of past responses to HA's	36%	60%	30%	17%	44%
Label management	30%	33%	43%	11%	28%
Extract product metadata into RIM systems	28%	40%	35%	22%	17%
Resource planning by analyzing pipeline, submission planning, and publishing	27%	20%	35%	33%	17%
Regulatory Intelligence Automation	24%	60%	22%	17%	6%
EMA SPOR Automation	23%	53%	17%	22%	6%
Use business rules engines for Regulatory Impact Assessments	20%	47%	17%	6%	17%
Machine translation	18%	47%	13%	6%	11%
Supply Release Automation	18%	33%	13%	11%	17%
Regulatory Pathways Analysis	8%	20%	4%	11%	0%

Figure 22: Advanced-Technology Regulatory Use Cases

So, what does regulatory need to do to use advanced technology with the aims of improving efficiency through reduction of manual efforts and of freeing critical resources for higher-value activities? We believe it is critical to develop a coordinated and comprehensive digital and intelligent automation strategy that includes foundational, strategic, and transactional elements. All three are ultimately required and must work in concert to be effective.

Regulatory Outsourcing Update

Regulatory dossier outsourcing continues to be a mature capability that results in both strong provider customer satisfaction levels and more options in the provider landscape. We have been tracking dossier outsourcing since 2007 (figure 23), but the past four years have not seen any meaningful change.

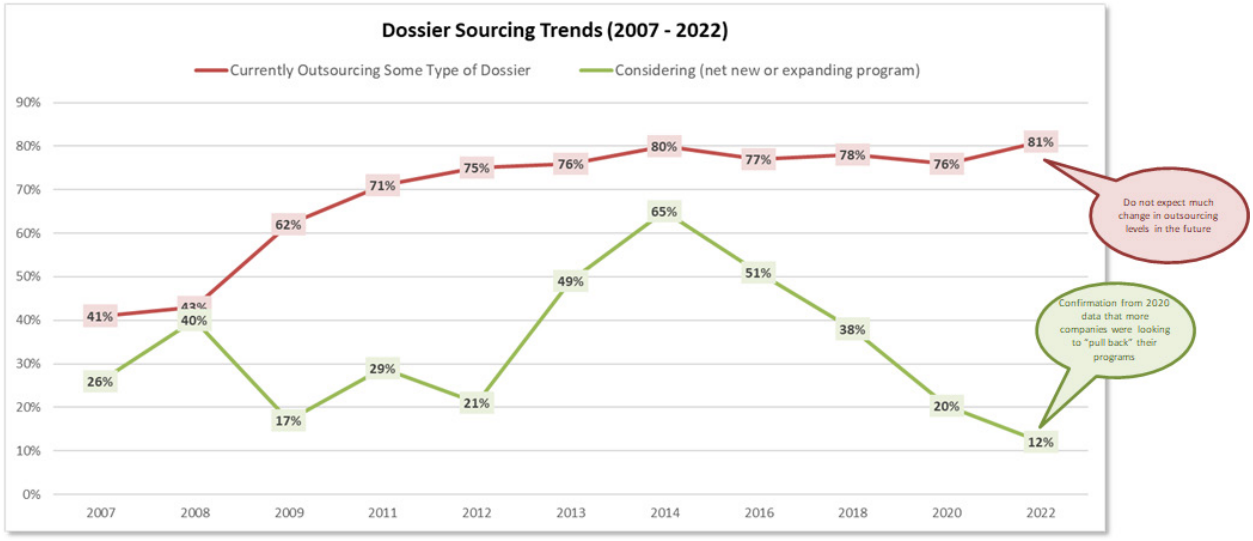


Figure 23: Dossier Outsourcing Trending Summary

In 2020, we observed for the first time the potential of a pullback in dossier outsourcing by small and mid-tier companies but not by the large multinationals. For the 2022 study, the number of companies expanding their outsourcing programs was about the same among participants that were planning to reduce dossier outsourcing.

Figure 24 depicts the tier and top-performer breakdown of most frequently outsourced regulatory activities along with the largest growth potential and most likely to reduce.

Dimension	Large (n = 16)	Mid-Tier (n = 23)	Small (n = 19)	Very Small (n = 18)	Top Performers (n=16)
Most Frequently Outsourced Regulatory Operations Activities (% today)	1) Maintenance of Investigational Applications (88%) 2) Maintenance of Marketing Applications (primary markets) (81%) 3) Maintenance of Marketing Applications (secondary markets) (75%)	1) Maintenance of Investigational Applications (52%) 2) Maintenance of Marketing Applications (secondary markets) (52%) 3) Maintenance of Marketing Applications (primary markets) (48%)	1) Initial Marketing Applications (secondary Markets (67%) 2) Maintenance of Marketing Applications (secondary markets) (56%) 3) Initial Investigational Applications (56%)	1) Maintenance of Investigational Applications (67%) 2) Initial Investigational Applications (67%) 3) Initial Marketing Applications (primary and secondary markets (50%)	1) Maintenance of Marketing Applications (secondary markets) (63%) 2) Initial Marketing Applications (secondary Markets (57%) 3) Maintenance of Investigational Applications (57%)
	• *Largest Growth Potential* – Structured Data Submissions (19%) • *Most Likely to Reduce* – Maintenance of Investigational Applications / Initial Mktg Application (primary) / Structured Data Submissions (13%)	• *Largest Growth Potential* – Initial Marketing Applications (secondary) / Structured Data Submissions (17%) • *Most Likely to Reduce* – Maintenance of Investigational Applications (17%)	• *Largest Growth Potential* – Maintenance of Marketing Applications (secondary markets) / Reg Ops Unit (11%) • *Most Likely to Reduce* – Initial and Maintenance of Marketing Applications (secondary markets) (17%)	• *Largest Growth Potential* – Structured Data Submissions (17%) • *Most Likely to Reduce* – Initial Marketing Applications (secondary markets) (17%)	• *Largest Growth Potential* – Minimal change expected • *Most Likely to Reduce* – Initial Marketing Applications and Maintenance (secondary markets) (19%)

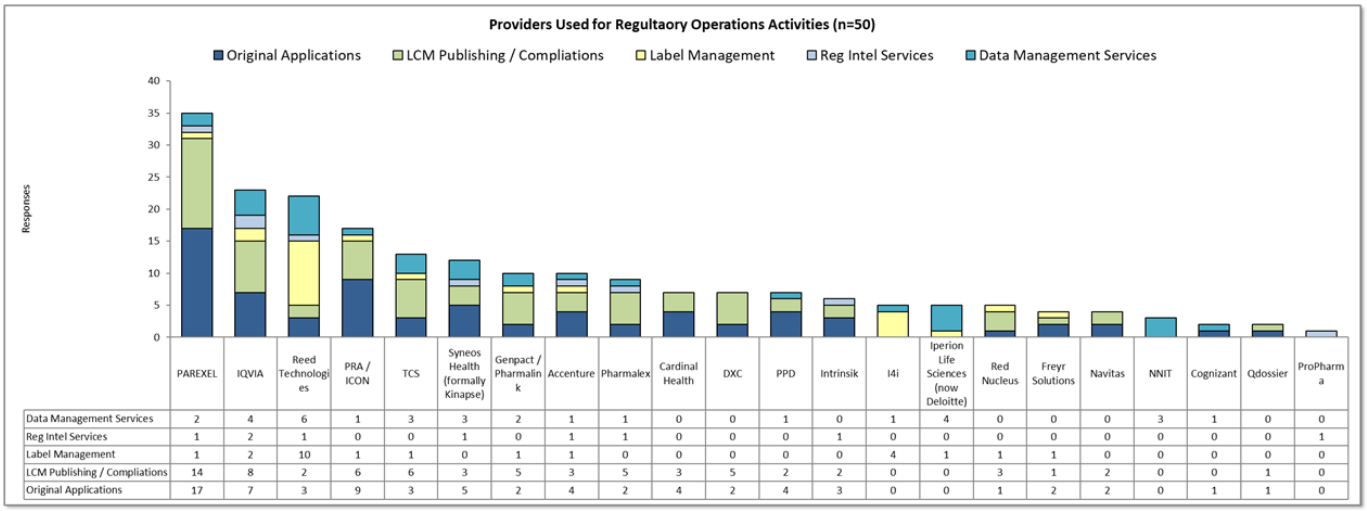
Figure 24: Regulatory-Operation-Activities-Outsourcing Summary

For 2022, we reintroduced the question on the outsourcing of specific regulatory roles (figure 25). The most-recent time we did such analysis was in 2018. There is commonality between the tiers for several specific roles—including regulatory intelligence, regulatory project managers, and regulatory strategists—which we expected.

Dimension	Large (n = 16)	Mid-Tier (n = 23)	Small (n = 19)	Very Small (n = 18)	Top Performers (n=16)
Most Frequently Outsourced Regulatory Roles (% today)	1) Regulatory Intelligence (88%) 2) Data Stewards for Regulatory Systems (81%) 3) Regulatory Strategist (75%)	1) Regulatory Intelligence (52%) 2) Regulatory Strategist (52%) 3) Data Stewards for Regulatory Systems (48%)	1) Regulatory Project Management (67%) 2) Regulatory Strategist (56%) 3) Data Entry / Management into Regulatory Systems (56%)	1) Regulatory Intelligence (67%) 2) Data Entry / Management into Regulatory Systems (67%) 3) Dossier Management / Regulatory Project Manager (50%)	1) Regulatory Strategist (63%) 2) Regulatory Intelligence (57%) 3) Regulatory Project Management (57%)
	• *Largest Growth Potential* – Regulatory Project Manager (13%) • *Most Likely to Reduce* – Regulatory Intelligence / Dossier Management (13%)	• *Largest Growth Potential* – Regulatory Project Manager (17%) • *Most Likely to Reduce* – Regulatory Intelligence (17%)	• *Largest Growth Potential* – Regulatory Strategist / Data Stewards (11%) • *Most Likely to Reduce* – Regulatory Strategist / Regulatory Project Management (17%)	• *Largest Growth Potential* – Minimal change expected • *Most Likely to Reduce* – Regulatory Project Management (17%)	• *Largest Growth Potential* – Minimal change expected • *Most Likely to Reduce* – Regulatory Project Manager / Regulatory Strategist (19%)

Figure 25: Regulatory-Role-Outsourcing Summary

Finally, we have been tracking regulatory service providers for six years, and for 2022, we added the *label management, regulatory intelligence, and data management services* to the analysis in addition to the historical dossier outsourcing analysis. Overall, the experience with most of these providers is positive, and details can be found in our *Regulatory Service Provider Market Report*.



	PAREXEL	IQVIA	Reed Technologies	PRA / ICON	TCS	Syneos Health (formally Kinapse)	Genpact / Pharmalink	Accenture	Pharmalex	Cardinal Health	DXC	PPD	Intrinsik	I4i	Iperion Life Sciences (now Deloitte)	Red Nucleus	Freyr Solutions	Navitas	NNIT	Cognizant	Qdossier	ProPharma
Data Management Services	2	4	6	1	3	3	2	1	1	0	0	1	0	1	4	0	0	0	3	1	0	0
Reg Intel Services	1	2	1	0	0	1	0	1	1	0	0	0	1	0	0	0	0	0	0	0	0	1
Label Management	1	2	10	1	1	0	1	1	0	0	0	0	0	4	1	1	1	0	0	0	0	0
LCM Publishing / Compliations	14	8	2	6	6	3	5	3	5	3	5	2	2	0	0	3	1	2	0	0	1	0
Original Applications	17	7	3	9	3	5	2	4	2	4	2	4	3	0	0	1	2	2	0	1	1	0

Figure 26: Regulatory Service Provider Usage Summary

Software Provider Landscape: Key Trends and Provider Update

The software provider landscape has gone through a major transition driven by technology, business, and economic factors. We estimate the total addressable market for the top 500 over a five-year period to be a $3.8-billion growing market driven by E2E RIM system and modernization spend. 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 end-to-end-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 strategy option, the clear direction is simplification at both the process and system layers. Based on our 2022 World Class RIM benchmark data, the percentages of participants that are highly likely to adopt a single platform for most capabilities (excludes publishing, label compliance, and regulatory intelligence) are:

Tier (2022 data/2020 data)

- Large = 69%/67%
- Mid-Tier = 52%/21%
- Small = 50%/54%
- Very Small = 61%/56%

Software Provider Summary

We realize not all providers can be reviewed in this section, and omission of a provider does not signal 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 samples are small.

We see two categories of software providers (figure 27) today and present our summary view of individual providers below.

Platform	
Amplexor	Generis (emerging)
ArisGlobal (emerging)	IQVIA
Ennov	PhlexGlobal (emerging)
Extedo (emerging with Generis)	Rimsys (emerging)
Fryer Solutions (emerging)	Veeva

Best of Breed Connected	
DXC Technology	OpenText/Documentum
Calyx (PAREXEL)	Sparta Systems
LORENZ	

Figure 27: Software Provider Categories

Platform Providers: This cohort has most of the 15 core RIM capabilities in their platforms. But even though most claim to have credible publishing and label compliance tracking capabilities, we believe they are several years away from a mature capability that could compete with the traditional, best-of-breed providers. This is also true with regulatory intelligence—an area in which no provider has a mature or innovative solution to date.

Emerging Platform Providers: This cohort has a traditional, best-of-breed base in either the content side or the data side of RIM and is in the process of expanding their solutions to encompass most RIM capabilities.

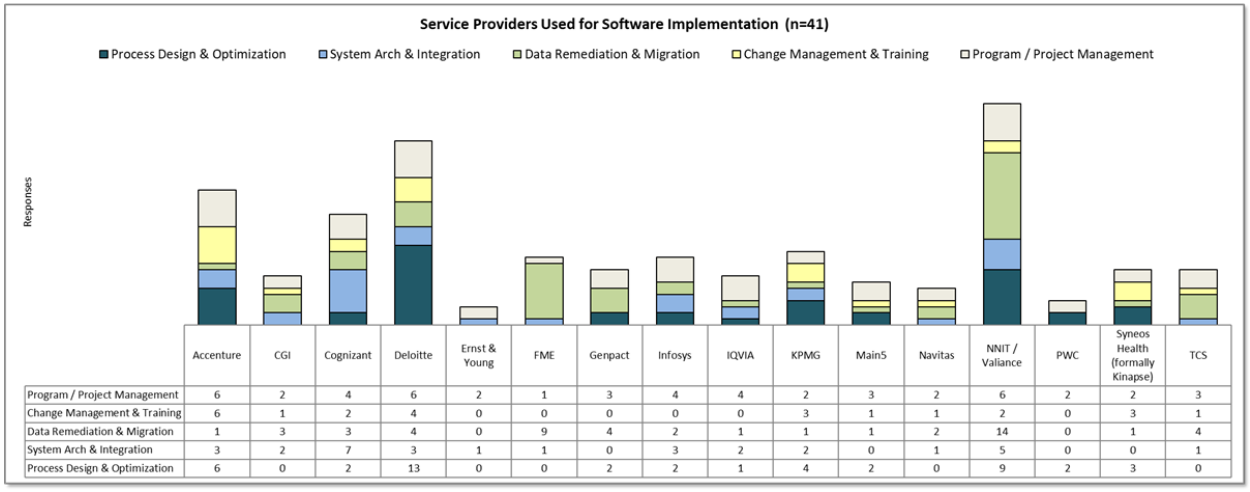
Best-of-Breed Connected: This cohort has strengths in a much smaller subset of what we consider E2E RIM, and it may be affected by the projected E2E RIM adoption trend in the 2021–25 timeframe.

Figure 28 depicts the 2022 market share summary. (Our market reports contain very detailed data about market share, customer satisfaction levels, and innovation perceptions.) Compared with 2020, we see Veeva gaining considerable share in the product registration area and LORENZ becoming the market leader for publishing in all tiers. The bold font depicts providers who have increased their market leadership and share for each solution type within a market tier since 2020.

Solution Type	Large Tier (n = 15)	Mid Tier (n = 23)	Small Tier (n = 16)	Very Small (n=18)
Submission Content Management	1) Veeva 2) Generis Cara or OpenText - Documentum	1) Veeva 2) OpenText -Documentum **3) SharePoint**	1) Veeva 2) SharePoint 3) OpenText - Documentum	1) Veeva 2) SharePoint 3) IQVIA
Publishing	**1) LORENZ** 2) Calyx 3) DXC Technology	1) LORENZ 2) Calyx **3) Veeva**	1) LORENZ **2) Calyx** 3) Extedo	1) LORENZ 2) IQVIA 3) DXC Technology or Veeva
Product Registration	**1) Veeva** 2) Calyx 3) ArisGlobal or **PhlexGlobal**	**1) Veeva** 2) Custom 3) ArisGlobal or Calyx	1) Veeva **or Custom** 2) Excel or **ArisGlobal or Calyx or IQVIA**	1) Veeva 2) Excel 3) Custom
Label Tracking	**1) Intagras** **2) Veeva** or Custom	**1) Veeva** 2) Sparta **3) ArisGlobal** / Intagras	1) Custom 2) Veeva 3) Intagras	1) Veeva 2) Reed Technology or Custom

Figure 28: Summary of Market Leaders by Size of Company (May 2020)

We have been tracking many important software implementation partners for four years, and they continue to have an overall positive experience by industry. Figure 29 depicts our standard implementation partner service-provider tracking list, but participants also listed ADEX, BASE life science, bridgingIT, Capgemini, Epista Life Science, eWORK, Inconsult, Iperion, NIIT, Pharma IT, Red Nucleus, Results WORKs, 7N, Spotline, and Tata Consultancy Services in the *Other, please specify* area.



	Accenture	CGI	Cognizant	Deloitte	Ernst & Young	FME	Genpact	Infosys	IQVIA	KPMG	Main5	Navitas	NNIT / Valiance	PWC	Syneos Health (formally Kinapse)	TCS
Program / Project Management	6	2	4	6	2	1	3	4	4	2	3	2	6	2	2	3
Change Management & Training	6	1	2	4	0	0	0	0	0	3	1	1	2	0	3	1
Data Remediation & Migration	1	3	3	4	0	9	4	2	1	1	1	2	14	0	1	4
System Arch & Integration	3	2	7	3	1	1	0	3	2	2	0	1	5	0	0	1
Process Design & Optimization	6	0	2	13	0	0	2	2	1	4	2	0	9	2	3	0

Figure 29: Software Implementation Partner Summary

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

The rest of this section provides analyst notes for software providers that we formally track and that receive annual reviews.

Amplexor Life Sciences continues to expand its end-to-end RIM solution with several new customers in 2021 and a solid customer retention rate. The company has invested heavily in improved dashboards and analytics; label management; electronic Common Technical Document (eCTD) publishing; and submission management and has substantially reduced the time it takes to upgrade customers to a new

version. The firm continues to invest in its quality solution for companies interested in a cross-functional standard platform.

We view Amplexor's data model as very strong, which lends itself to SPOR/IDMP and structured-content management. The company recently released improved referential data management, which is important for cross-functional information system sharing, and it is well prepared for the evolving EMA SPOR/IDMP requirements.

ArisGlobal has been a key provider in the R&D space for more than 30 years by providing long-standing solutions in the areas of pharmacovigilance and regulatory as well as clinical and medical affairs. Recent investment funding has bolstered the company's regulatory business, including investment in team growth and plans for expanding integrations across the drug development life cycle, which we are looking forward to seeing play out. ArisGlobal added several new customers in the past 12 months and continues to enjoy a high customer retention rate.

The company has brought several new capabilities to market, (1) with customers going into production during the past year with SPOR integration capabilities (RMS and OMS), (2) by achieving full integration of the firm's LifeSphere EasyDocs document management system, (3) by adhering to Brexit compliance, and (4) by adding tobacco product and process support. And plans to improve medical device capabilities, cross-platform workflow automations and connections, the establishment of a dossier offering for emerging and small-to-medium-sized businesses (SMBs), and a special focus on customer satisfaction will bring value to both existing and new customers in the coming year.

Calyx has provided regulatory solutions for industry for nearly 20 years and is one of the longest-standing and best-established publishing and registration management providers. Extraction of the software arm of Parexel into Calyx in early 2021 enabled a focus on software solutions, which creates an opportunity for renewed emphasis on key regulatory solutions. We do not have information about customer acquisition or retention during 2021.

Recent focus areas of Calyx solutions have included establishing a select offering for SMB publishing, incorporating IDMP concepts into the native registration management solution, and improving system efficiency through the firm's partnership with Microsoft on Azure, including moving long-standing customers to the firm's cloud solution. During the next 12 months, we anticipate (1) continued improvements to the publishing solution, (2) the establishment of eCTD 4.0 capabilities, and (3) maturing IDMP capabilities while the company continues taking advantage of the capabilities and benefits of its cloud-hosted solutions.

Ennov continues to grow its regulatory solution business, and it also offers safety/pharmacovigilance, clinical, and quality modules. The company serves primarily the life sciences industry but also has a presence in the hospital market. Ennov continues adding new customers, has a strong customer retention rate, and maintains the high ranking of number two in our Innovation Index.

To support its growth, the company opened an office in Hanoi last year to support the Asia Pacific region and help develop a next-generation platform. The firm's product road map focuses on evolving data quality and consistency, data retrieval and entry, dossier management, structured data submission, and

publishing. Ennov is well prepared for SPOR/IDMP and has an IDMP service for data preparation. The company is extending its end-to-end RIM scope to include medical devices, cosmetics, and consumer products.

EXTEDO has served both industry and health authorities for 25 years and has a substantial publishing business in the small and medium tiers as well as a smaller market share in the large tier. The company has added many new customers—including large-tier companies—in the past 12 months in both industry markets and health authority markets and has a very high retention rate. Working with so many health authorities results in gaining intimate knowledge of regulatory requirements as well as being prepared to quickly meet new requirements— a significant advantage for the company's customers.

EXTEDO has a strategic relationship with Generis that brings a true end-to-end RIM solution (best of both providers) and has demonstrated the combined value by way of many new customers' going into production during the past year, with impressive business benefits such as reduced time to market driven by a modern dossier management process and technology. We expect EXTEDO to continue to be successful in the market based on the firm's diverse industry and health authority portfolio and its strategic partnership with Generis.

Freyr has been a provider of services in life sciences for more than 10 years. In recent years, the firm has brought that experience into the software space: first in publishing, and more recently, in registration management/RIM, in labeling and artwork, and in regulatory intelligence. We recently began to follow the firm and have been impressed by what we've seen—especially in the areas of label management software and services. Of particular interest to us is the company's impressive entry into the regulatory intelligence space with both software and data services, which are already being implemented at a top pharma company. In the past year, Freyr added quite a few new customers across all of its capabilities, and it maintains full retention of existing customers.

In the next 18 months, Freyr plans enhancements to its publishing capability, including establishing eCTD 4.0 readiness, medical device templates for US and European Union submissions, and collaborative submission review processes. The company also plans to establish automation for the management of health authority correspondence and responses, to continue to mature its registration management capabilities, and to establish integrated regulatory intelligence within its RIM system. We are very interested to see how Freyr evolves in the next couple of years.

Generis has been supporting the life sciences regulatory environment for 25 years; it continues to enjoy high customer satisfaction levels; and it ranks high in our Innovation Index. Although its heritage is more on the content side, the company has expanded successfully into the data side, with a full E2E RIM platform that has seen many successful deployments recently. Numbers of new customers have increased significantly in the past two years, and although the company does support other highly regulated industries, life sciences is the firm's primary focus.

Generis has also had successful deployments in quality, medical information, risk management, eTMF, and legal and contracts and is now supporting label management. The company also will be supporting safety/pharmacovigilance and laboratory management in the near term. Generis is also investing in

advanced technologies such as structure content authoring, natural language processing, and artificial intelligence and is ready to support the SPOR/IDMP requirement.

IQVIA continues investment in its regulatory, safety, and quality solutions along with deepening its artificial-intelligence solutions that target both regulatory and safety. The firm's technology strategy is a stepwise approach that focuses first on foundational automation and then on intelligent automation, with artificial intelligence driving long-term automation goals.

The firm continues to have a presence in the areas of content management, publishing, and registration management in the small and very small tiers and has a powerful regulatory intelligence database covering 110 markets for all tiers. The company is investing in publishing, SPOR/IDMP, natural-language-processing data extraction, label management, and component authoring with its RIM smart platform. IQVIA also has a strong regulatory outsourcing service for publishing and data management that saw an increase in activity for 2022.

LORENZ continues to have the highest customer satisfaction score of all software providers we track that have at least four ratings. The company has had very high customer retention rates both in the past year and during the past five years. It shows significant growth in terms of midsize and large customers and very substantial growth in number of small-company customers. In recent years, LORENZ has diversified its customer base by way of the addition of many global health authorities. The firm's RIM platform, including publishing, was recently enhanced to include support for eCTD v4 in Japan, which added the ability to reduce document redundancy across the regulatory life cycle and which added support for central controlled vocabulary management. In addition, the company increased its services and implementation support in the areas of data migration and publishing.

Near-term priorities include IDMP publishing support and a unified data model for RIM capabilities throughout the regulatory life cycle. Customers across multiple sectors have seen measurable improvements with regard to time spent (reduced) and efficiency (increased), especially in preparing and managing submissions. The firm's end-to-end RIM platform also supports integration with other products for capabilities for which there is a legacy best-of-breed product in place.

Phlexglobal: In 2020, Phlexglobal acquired Cunesoft, and the result has been strong. Phlexglobal made heavy investments in the regulatory offerings Cunesoft brought to the table, and it adopted Cunesoft's advanced technology into its clinical solutions. In the past 12 months, Phlexglobal added several new regulatory customers for its PhlexRIM solution and enjoyed high customer retention rates. The recent merger between Phlexglobal and PharmaLex brings together two organizations with strong regulatory and clinical services in addition to an innovative technology platform. It will be interesting to see how they progress.

On the capabilities side, Phlexglobal has paid particular attention to the needs of small and medium-sized businesses, with plans to provide preconfigured, out-of-the-box solutions to streamline and simplify implementation. The company's artificial-intelligence capabilities will be further leveraged to automatically extract relevant data for RIM and IDMP solutions, and the firm is planning a regulatory data explorer, application-programming-interface-enabled-data provision for consumption by other

systems or data lakes. Leveraging PharmaLex's expertise, Phlexglobal is also eyeing regulatory intelligence as well as expansion to include medical device support in its RIM solution.

Rimsys: We started tracking Rimsys in 2021 and have become very impressed with this young company founded in 2017 by regulatory affairs professionals who focus on the medtech space and are well funded. In a short time frame, Rimsys has gained many new large, medical-device customers and several mid-tier customers and is enjoying very high retention rates. The company is focusing on registration and technical file management, new-submission authoring, and publishing of features, including market entrance requirements for over 100 countries, which is a built-in regulatory intelligence capability.

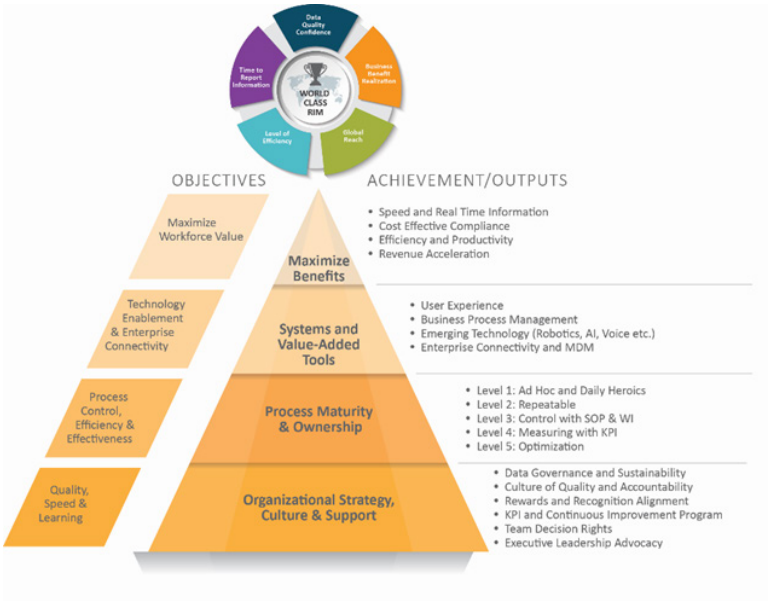
The firm's mission is to modernize medtech regulatory affairs while also ensuring cost-effective compliance with requirements such as Unique Device Identification. Changes to workflow automation based on regulatory or standards changes, decision trees linked to market entrance requirements and associated digital government templates, and collaborative submission authoring are just a few examples. Rimsys is expanding into postmarket surveillance management, including the authoring and submission of postmarket surveillance reports and periodic safety update reports. During our briefing, many examples of business outcomes from client experiences were provided which supports our impression of a business-outcome-based software solution provider.

Veeva continues to rapidly gain market share and has retained the number one ranking in our Innovation Index. The company has added a significant number of new regulatory clients, expanded the number of Vaults in existing clients, and made good strides in the clinical, safety, and quality domains. Veeva is focusing on iterating and bringing additional automation to active dossiers, global content plans, continuous publishing, labeling, and health authority correspondence and commitment management processes.

Another critical focus at Veeva is on improvement in cross-Vault connections to further enable end-to-end process work, especially in the change control, TMF to dossier submission, and ad/promo (e.g., generation of 2,253 compliance packages for FDA submission) processes. The company has a strong customer advisory board that guides strategic investments and taps into deep industry knowledge. Veeva has hired a considerable number of new staff to support its growing customer base and may experience the common high-growth challenge of rapid onboarding.

Study Conclusion

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



- Top performance is derived from excellence in the organizational elements such as data governance, data quality sustainability, continuous improvement with a strategic KPI program coupled with global process maturity. Such a foundation enables an organization to maximize its technology investments and business benefits.
- A culture of quality is critical to long-term data quality confidence; this is achieved by executive and key stakeholder advocacy and reward / recognition systems alignment to regulatory quality goals.
- Working to improve "the last mile" or innovation at the local affiliate level is critical to fully realize global RIM adoption.
- High performance is achieved over time and requires executive advocacy for large-scale change along with an effective continuous improvement program for gradual incremental change.

White Paper Authors

Steve Gens is a survey cofounder, with the first industry survey having been conducted in 2007. The 2022 World Class RIM will be the 38th survey conducted under Steve's leadership. Steve has over 30 years of business experience, with the majority of it in the biopharmaceutical and healthcare industries. His early career was spent at Johnson & Johnson, after which he moved into the area of consulting by managing several healthcare consulting practices for Booz Allen Hamilton and First Consulting Group.

Steve has deep experience in strategy formulation and implementation, organization development and performance, industry benchmarking, information management strategy, and facilitation of strategic change. He consults with 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. 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 of K2 Consulting—a survey team since 2019—has over 25 years' experience in the pharmaceutical industry, leading both IT and RIM/regulatory operations organizations at several companies, including Wyeth, Pfizer, Shire, and Teva. She 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. Kelly is president of IRISS (www.iriss-forum.org) and is on the leadership team of IRISS's IDMP Topic Group.

Greg Brolund has served on the survey team since 2009. He is a global pharma 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 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 & 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.

Sarah Powell has been on the survey team since 2015 is president of Powell Regulatory Services. She has over 30 years of experience in the life sciences industry's areas of clinical, quality control, regulatory affairs, and regulatory operations. In the past 16 years as a consultant, she has assisted clients in making regulatory process improvements, in achieving standards development, in defining filing strategies, and in writing and reviewing submission content. Sarah

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 is a core member of the Gens & Associates team, who has over 15 years of experience in the healthcare and pharmaceutical industries, leading and managing complex interdisciplinary projects. She was a research scientist at Regeneron Pharmaceuticals and Children's Hospital of Philadelphia before transitioning to consulting work 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.

has extensive experience in conducting projects related to the design and implementation of regulatory solutions in the areas of document management, submission planning, publishing, and registration management and was an executive at Chiron, First Consulting Group, and Parexel. Sarah has a Bachelor of Science in nutrition science from the University of California, Davis. She is Regulatory Affairs Certified in the United States and the European Union and is a Regulatory Affairs Professionals Society Fellow.

Appendix

15 RIM Categories

1. Submission Forecasting and 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
6. Product Registration Management
7. Health Authority Commitment Management
8. Health Authority Interactions (Q&A, correspondence)
9. Regulatory 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

11 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 Lake (pooling from multiple systems)

Providers in Innovation Rating (sorted alphabetically)

1. Amplexor
2. ArisGlobal
3. Calyx (formerly Parexel)
4. DDI
5. DXC Technology
6. Ennov
7. EXTEDO
8. Generis
9. i4i
10. Instem
11. Intagras
12. Kalypso
13. IQVIA
14. LORENZ
15. Microsoft
16. OpenText (Documentum)
17. Orion (includes Cabeus)
18. Phlexglobal (includes Cunesoft)
19. RegDocs 365
20. Rimsys
21. Schlafender Hase (Text Verification Tool)
22. Sparta
23. Veeva

Gens & Associates Inc. Recent Benchmark History

1) 2013 *Managing Regulatory Information as a Corporate Asset (n = 37)*
2) 2013 *Regulatory Operations Pulse*
3) 2013 *CTA Pulse*
4) 2013 *EDMS and Digital Archive: One and the same?*
5) 2014 *Regulatory IT Resource Pulse*
6) 2014 *Next Generation RIM and Regulatory Intelligence: Strategy, Investments, and Status (n = 41)*
7) 2015 *Product Registration Investment Pulse*
8) 2015 *Next Generation Content Management (n = 21)*
9) 2015 *Addressable Market update (solution and services)*
10) 2015 *Legacy Product Outsourcing Pulse Survey*
11) 2016 *Pursuing World Class RIM: Strategy, Measures, and Priorities (n = 54)*
12) 2016 *Enterprise Content Management Governance Structure Pulse Survey*
13) 2017 *Safety Systems Trends: Innovation, Operating Model and Growing TCO Pulse (n = 17)*
14) 2017 *Regulatory Services and Software Addressable Market Analysis Update (top 500)*
15) 2018 *Pursuing World Class RIM: Connections to QMS, Supply Release and Product Change (n = 72)*
16) 2018 *Submission Content Management Capability Change Investment Pulse (n = 10) – Top 30*
17) 2020 *World Class RIM: IS Industry at a Performance Tipping Point (n = 70)*
18) 2020 *COVID-19 Regulatory Impact Pulse Survey (n = 245) – Individual Response Survey*
19) 2021 *Structure Content Authoring (n = 25) Pulse Survey*
20) 2021 *IDMP/SPOR Architecture Pulse Survey and Software Provider Review*
21) 2022 *World Class RIM: Accelerating Business Value (n = 76)*
22) 2022 Regulatory Intelligence Pulse Study (open)