2020 World Class Regulatory Information Management (RIM) Whitepaper

Fall Edition - Based on our *2020 World Class RIM: Is Industry at a Performance Tipping Point?* Study

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Introduction

The key question to this year's World Class RIM study was, "is industry at a performance tipping point?" We are pleased to report the answer is a resounding "yes" as 13 organizations achieved either Strong Performance or World Class levels. Regulatory Information Management (RIM) programs are experiencing a crescendo of true global deployment driven by process optimization and new systems, business benefit realization, and a focus on data quality sustainability as an organizational competency.

This paper provides insights from our 2020 study, explores pathways to achieving a high performing RIM program, and highlights learnings from the study top performers. We review the current industry status, key trends and investment priorities, and provide a comprehensive update on the software and service provider landscape. Our two new sections explore RIM connectivity to other critical functions and the future of structured data submissions. Key study take-aways to be explored are:

1) Data quality confidence levels continue to be an industry challenge; companies need to adopt data quality sustainability as a core organizational competency reflecting a "culture of quality."
2) Regulatory information is beginning to be viewed and valued as a strategic asset as industry prepares for structured data submission and connects RIM with many other functional areas.
3) The RIM provider landscape is shifting with a change in leadership and innovation approaches.
4) There is no correlation between top performers to any one software provider or system strategy; they excel at the process and organizational work to maximize technology investment.
5) Top performer traits include global RIM adoption, data driven continuous improvement, process maturity, high data quality confidence reflecting a culture of quality.

The information and graphs are primarily based on the 2020 World Class RIM study results coupled with key learnings from survey debrief sessions, client work and our insights. The paper structure is:

- Demographics and Survey Design Process
- Industry Status: World Class RIM and Investment Priority
- The Path to High Performance
- Preparing for the future of Structured Data Submissions
- Advanced Technology and RIM Connection Status and Projections
- Regulatory Provider Landscape: Key Trends and Performance Status

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


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Since 2009


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New to the Team


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Survey Demographics and Design Strategy

We had 66 companies participated in the study this spring. Due to the COVID-19 pandemic, we reopened the survey in late summer to allow more companies to participate and expect to have a study amendment in early 2021.

This is our fifth large RIM study since 2013 and the participant diversity has increased. They represent large, mid-tier and smaller organizations (see Figure 1). These categories are determined by revenue size through the annual Pharmaceutical Executive Top 50 publication. Growing the diversity of companies with product portfolios such as device, consumer, and agricultural is important to our research. We also had a sizable increase of very small companies (those with 0 – 3 products on the market) as they 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 by geographic area.

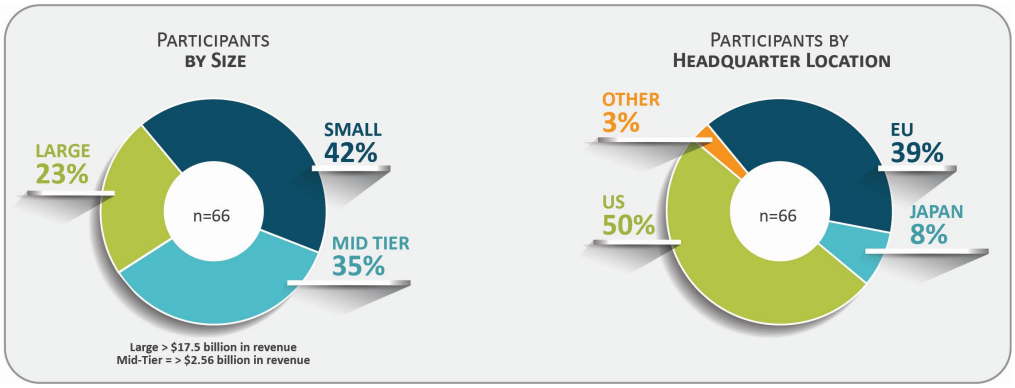


Figure 1: 2020 Survey Demographics

We appreciate the 39 organizations (see figure 2) that contributed to strengthening the survey design. They included 29 companies representing industry that participated in 5 global design sessions in the fall of 2019. We also had many of the prominent regulatory software providers and our two strategic consulting partners, Iperion and Grant Thornton Life Sciences, review and provide feedback to the draft design. In total, we had 72 individuals participate in our survey design process.

Figure 2: 2020 Survey Contributors

Industry Status: World Class RIM and Investment Priorities

Industry continues to invest heavily in RIM capabilities, strategic regulatory initiatives, and connecting RIM to the enterprise. Figure 3 depicts priority RIM capability and connection point investments by size of company in the near and longer-term. We asked a new question on strategic regulatory initiatives this year and found that at least 60% of industry is currently investing in continuous improvement, cross functional process optimization (labeling, variation management), global dossier strategy, regulatory resource management, and strategic data management.

Investment Period	Large (n = 15)	Mid-Tier (n = 23)	Small (n = 28)
Highest Change in 2018	Data Management (65%)	Dossier Management (50%)	Labeling (44%)
Highest Focus in 2020 Base RIM Capability Connection Point	Dossier Management (60%) eTMF Connection (27%)	Reporting/Dashboards/analytics (48%) Product Supply Release, Data Lakes (both 9%)	Reporting/Dashboards/Analytics (54%) Dossier Management (50%) eTMF Connection (12%)
RIM Base Capability Priority Investments for 2021 – 2022	1) Submission Document Management (40%) 2) Submission Forecasting (40%) 3) Label Compliance (33%) 4) Regulatory Archive (33%) 5) Submission Planning & Tracking (33%) 6) HA Interactions (33%)	1) Dossier Management (39%) 2) Registration Management (35%) 3) HA Interactions (35%) 4) Label Compliance Tracking (35%)	1) Label Compliance Tracking (36%) 2) Registration Management (32%) 3) HA Commitment Management (25%) 4) Regulatory Intelligence (25%)
RIM Connection Points Priority Investments for 2021 – 2022	1) Label Artwork Management (33%) 2) Safety / PV , R&D Portfolio Planning, MDM (all 27%)	1) Data Lakes (35%) 2) Product Change Control (35%) 3) Safety/PV, Artwork Management, MDM (all 30%)	1) Product Change Control (35%) 2) Safety/PV (35%) 3) eTMF, Label Artwork Management (both 31%)

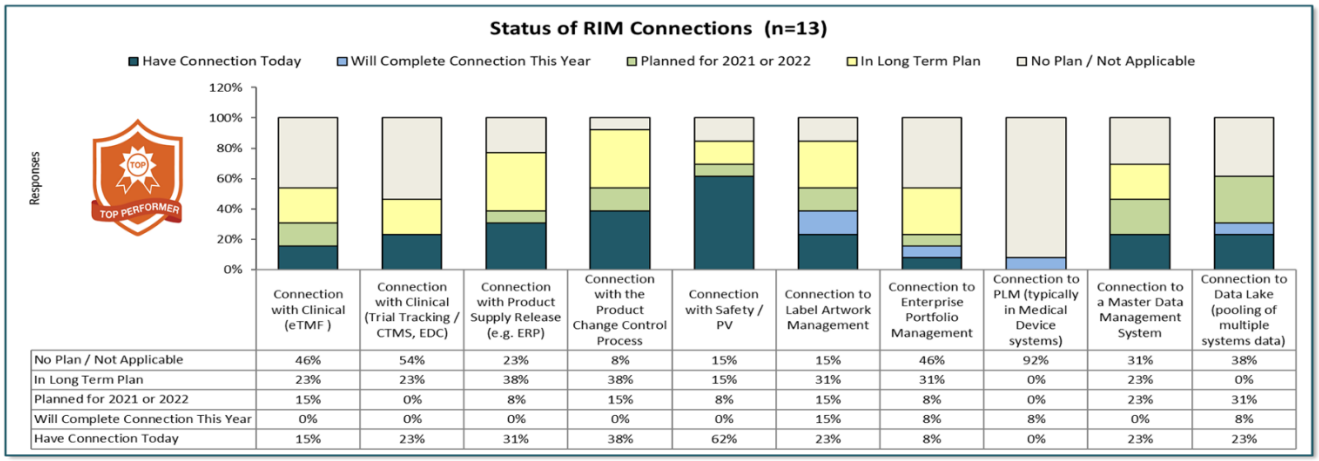
Figure 3: Investment Priority by Tier Analysis

We greatly expanded the RIM connection points (see appendix for a complete list) and introduced a connection maturity model that explores terminology management, business process automation, and information reporting. Connecting two systems is straightforward, it is the reconciliation of terminology, streamlining the process, and visualizing the data that brings the value to the connection.

Enterprise connectivity and cross functional information throughput is growing in priority, driven by a focus on end to end process optimization and data analytics. While most of industry has very little RIM connections to other functional areas today, the study Top Performers, defined as achieving World Class or Strong Performance levels (n = 13), are far more connected than all other participants (see figure 4). This includes:

1) Connection with Safety/PV (62% for Top Performers, 8% for all others)
2) Connection with the Product Change Control Process (38% for Top Performers, 13% for all others)
3) Connection with Product Supply Release (31% for Top Performers, 9% for all others)

We see Top Performers as a predictor of RIM connectivity value and looking to their plans for 2021 and 2022, we see priority RIM connection investments to Data Lakes, Master Data Management, and Artwork Management.



	Connection with Clinical (eTMF)	Connection with Clinical (Trial Tracking / CTMS, EDC)	Connection with Product Supply Release (e.g. ERP)	Connection with the Product Change Control Process	Connection with Safety / PV	Connection to Label Artwork Management	Connection to Enterprise Portfolio Management	Connection to PLM (typically in Medical Device systems)	Connection to a Master Data Management System	Connection to Data Lake (pooling of multiple systems data)
No Plan / Not Applicable	46%	54%	23%	8%	15%	15%	46%	92%	31%	38%
In Long Term Plan	23%	23%	38%	38%	15%	31%	31%	0%	23%	0%
Planned for 2021 or 2022	15%	0%	8%	15%	8%	15%	8%	0%	23%	31%
Will Complete Connection This Year	0%	0%	0%	0%	0%	15%	8%	8%	0%	8%
Have Connection Today	15%	23%	31%	38%	62%	23%	8%	0%	23%	23%

Figure 4: Top Performer RIM Connection Status

World Class RIM and Strong Performance Industry Status

We created the World Class RIM performance model with 35 companies between 2015 and 2017. For 2020, we slightly expanded the number of key performance indicators which reside in the Business Benefit Realization category which are indicators of a World Class organization.

Figure 5: World Class RIM Categories

World Class RIM – Five Elements, Ten Questions

The following describes the core 5 World Class RIM categories (see figure 5) with the number of data points (in parenthesis) used for this industry benchmark.

1) **Data Quality Confidence (11**) - It is one thing to have an authoritative source, but what is your confidence in the quality of the data in your authoritative source? This category is heavily weighted in our world class algorithm and is foundational to RIM performance.

2) **Business Benefit Realization (42)** – Comprised of 15 business benefit realization status, 30 key performance metrics usage, continuous improvement program status, and operating cost understanding.

3) **Global Reach: Global System Deployment Status (6) -** World Class means the "world" can access and utilize the core RIM capabilities in at least 75% of the affiliate offices (we account for the agent/distributor network).

4) **Level of Efficiency (18)** - Evaluates the effective utilization of resources, repeatability of process, and low error rates to achieve regulatory goals of the 15 RIM capabilities and 3 connection points (see

appendix for listing). We use a 4-point scale so participants who are unsure must decide whether they lean toward efficient or not efficient.

5) **Time to Report Information: Provide Accurate Reporting to Common Regulatory Questions (9)** – This is a very telling measure with a clear correlation to data quality confidence levels. We have 9 common regulatory questions; for example, what products are registered in what countries. Participants indicate if they can answer each question in real-time, within a day, multiple days, or a week or more.

Figure 6 depicts the placement of the 66 spring and 3 fall participants and their relationship to their tier average, the strong performance band, and the world class level. Two companies achieved World Class and 11 are in the Strong Performance band. We interviewed the top 3 performers from the study to congratulate them on their achievement and explored areas that were hard to measure, such as executive leadership advocacy and a culture of quality which are reviewed in the next section. Regarding our study title, "is industry at a performance tipping point", the improved performance of the mid-tier and large company performance averages, (orange line below) when compared to 2018, was significant.

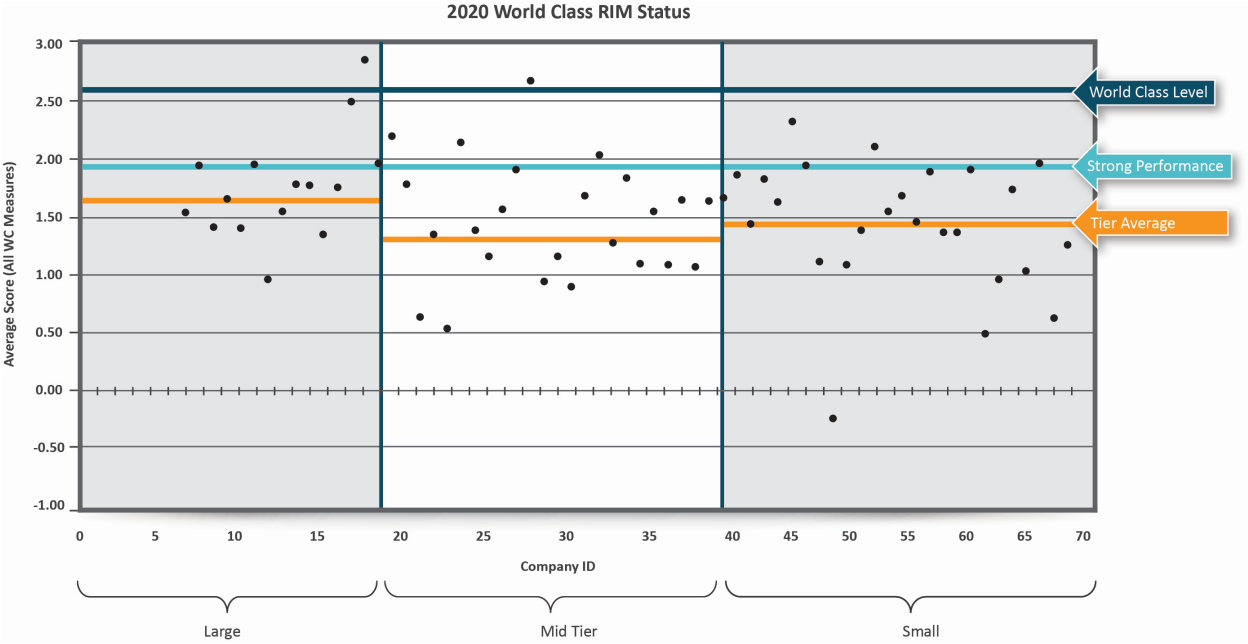


Figure 6: World Class RIM Benchmark Results

To further support evidence of increased industry performance levels, figure 7 provides a performance comparison of 2018 to 2020 and 2020 Top Performers to everyone else. While most areas have seen incremental improvement since 2018, it was the adoption of global systems that saw a significant increase in key areas such as submission content management, registration management, health authority commitment tracking, and label compliance tracking. We were surprised to see data quality

levels about the same compared to 2018 indicating significant data quality work is still required for most organizations.

Category	2020 - Top Performers	2020 – All Participants	2018 – All Participants
RIM capability efficiency – content centric	77%	54%	51%
RIM capability efficiency – data centric	82%	42%	38%
Continuous Improvement Program	92%	56%	46%
Cost Understanding	72%	39%	36%
Percentage who have real-time information	57%	37%	31%
High Data Quality Confidence	62%	35%	31%

Figure 7: Performance Comparison

The Path to High Performance

Since 2014, our benchmark data has shown there is no correlation between top performers and any one regulatory solution provider *or* system strategy (platform vs. simplified best of breed). This indicates RIM high performance is not achieved by just investing in a particular tool or with a specific software provider, instead performance improvement happens through intentional and focused work on the organizational and process levels.

This year we introduced our RIM Performance Framework (see figure 8), summarizing our understanding of 'what works' for the path to high performance from over 100 companies in our World Class RIM benchmark and 15 years of regulatory consulting projects. The framework consists of 4 levels and considerations at each level to optimize RIM performance. Starting from the base layer and moving up the pyramid, our framework shows how the combination of strong foundational organizational elements and process maturity levels (*how* the work gets done) help drive performance and value out of the chosen RIM investments so that business benefits can be achieved.

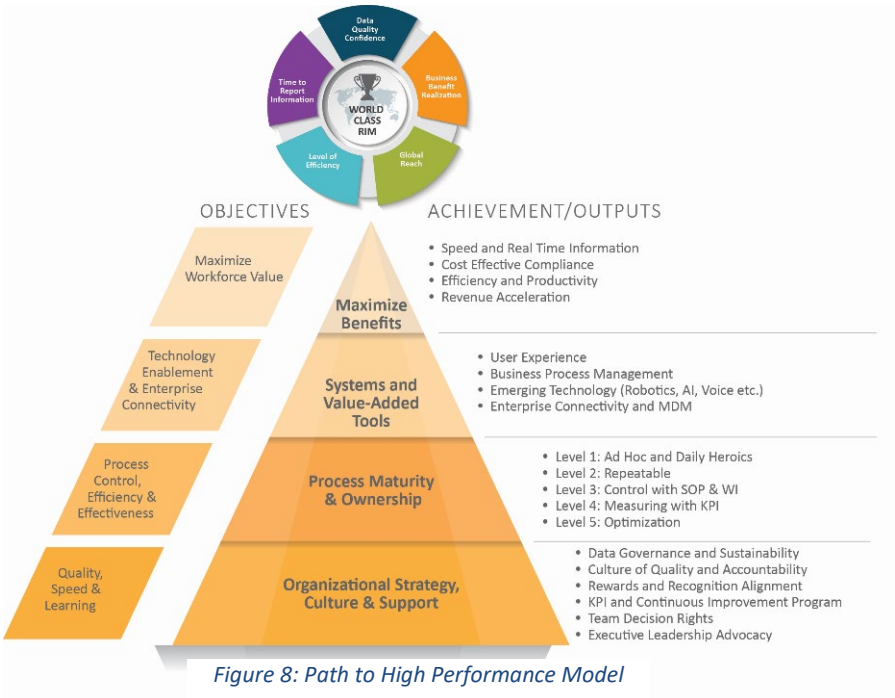


Figure 8: Path to High Performance Model

We looked closely at this year's Top Performers and examined their traits to better understand the current behaviors and practices that led to higher performance. Top performers:

- Are twice as efficient at data centric capabilities (e.g. registration data)
- Are 28% more efficient on content centric capabilities (e.g. submission content)
- Have higher data quality levels
- Most likely have achieved Global RIM adoption (90%)
- Have higher software provider customer satisfaction
- Are better at connecting to other enterprise capabilities
- Are much further along on structured data submissions and using advanced technologies

The difference between top performers and everyone else is clear, so what can others learn from them? The answers start at the base layer of the RIM Performance Framework. There are 5 critical organizational elements that make up the foundation of the pyramid: Strategy, Teaming, Culture, Organizational Processes and Leadership styles (figure 9). We believe these elements are the drivers of speed, agility, and resilience at any company. Although these elements will continually be impacted by internal and external factors, finding alignment within these organizational elements creates the environment that supports performance improvement. Creating an optimal environment sets the foundation and increases the likelihood that implementation of your RIM investments will be adopted, effective, and sustainable. What we have learned from our top performers is that it takes time and effort to find the alignment; intentional and focused work is required.

Figure 9: Five Organizational Elements for High Performance

The 5 organizational elements focus on the importance of quality, speed, and learning. Since challenges and successes are unique for every organization, we recommend these common practices to help organizations become more agile by shifting to an 'explorer' mindset where they can learn to adjust and self-correct quickly when needed.

Strategies for high performing RIM organizations include the use of continuous improvement programs with key performance indicators and metrics. Having a dedicated RIM group, data standards and quality governance in place, along with a solid line affiliate reporting relationship are also important strategies that positively impact performance.

The 'right' **teaming dynamic** is essential for reaching and sustaining improvement goals since collaboration also needs cooperation to be successful. The right people, with applicable skillsets and knowledge, are critical for getting the work done. Teams should have clearly delegated decision rights to take action, as well as a clear sense of ownership and responsibility for their work. Teaming, done right, allows people to build on and build up trust, which leads to a culture of innovation and learning.

A **culture of innovation and learning** describes an agile organization. Since markets and regulatory environments are constantly in flux, the ability to be flexible and quickly self-correct becomes an important advantage for companies today. Culture impacts performance in a big way because it often explains or predicts how and why things get done in an organization. Culture also runs deep with an element of familiarity that ties people within an organization together. It is strong enough to be used as justification for decisions, even if the argument is unclear. How often do people shy away from suggestions or ideas because "that's just not how we do things around here". On the other hand, culture is also strong enough to motivate teams toward specific goals. For example, consensus driven organizations planning to give decision rights at an individual or team level can provide or showcase an 'all in favor of' change for the decision to motivate those individuals or teams to accept their delegated decision rights.

In our experience, the most critical **organizational process** is aligning rewards and recognition systems with data quality expectations to support building a "culture of quality". While it is important for individuals to understand the objectives of their role and meet annual work-related goals, the use of recognition is ultimately the more powerful tool to encourage performing tasks at a 'culture of quality' level. It is not uncommon for organizations to approach data quality challenges in a punitive manner, often highlighting the problematic and ignoring the successes. This unbalanced approach can contribute to a culture of inaction or exasperation. Aligning rewards and recognition with data quality expectations starts with publicly recognizing areas of data quality excellence and rewarding those individuals or teams performing well. Nurture and encourage a learning community so that successes and strategies for success can be shared, especially to teams that might be struggling. This process takes the focus away from punishment and failures, shines a light on what is possible and sets a quality standard for all to achieve.

Another organizational process for consideration is the decision-making process for implementation teams and data governance groups. Having the process and empowering teams to take those actions is crucial for any data governance mobilization since having clear decision rights and permission to move quickly on data quality standards and data quality performance levels leads to the foundational 'culture of quality'.

During conversations with top performers, each talked about the importance of **public senior executive leadership advocacy** and how it was critical for their success. A good leader is not just a spokesperson and approver of strategic initiatives; they also move things along by shepherding progress while enabling their teams. Notable leadership styles for high performing teams include having effective communication skills and the ability to champion and empower their teams while also promoting psychological safety by having tolerance for those taking informed risks, even if unsuccessful.

These 5 organizational elements are critical to enable performance improvements. Imagine each of these elements as a set of compasses where the goal is to get all 5 needles pointed toward the same direction. Finding the alignment between these organizational elements will take concerted effort and deliberate practice. The result will be a focused organization with a solid foundation and an optimized environment, ready to rapidly proceed on the path to high performance.

Preparing for the future of Structured Data Submissions

Structured Data Submissions are currently a hot topic with several health authority initiatives on the horizon. These include PQ/CMC from the FDA, Structured Product Monograph (SPM) from Health Canada, EUDAMED for medical device data in the EU, and of course the one on everyone's mind this year: EMA's IDMP/SPOR. This year we've devoted a section of the survey to consider Structured Data Submissions from 3 three perspectives: (1) understanding what companies are doing today for existing requirements like SPL and xEVMPD, (2) looking at the strategies companies are planning to leverage as they implement capabilities to support upcoming requirements, and (3) looking at tactical plans to prepare for upcoming requirements.

Historically, Industry approached structured data submission requirements from health authorities on a case-by-case basis. The necessary solution for each requirement was put in place to ensure compliance and companies generally did not view these requirements as impactful to their overall strategies for managing RIM data. This is demonstrated in the survey results for 2 requirements which have been in place for many years: SPL and xEVMPD. SPL-based submission preparations are outsourced by a high proportion of the companies that have an SPL reporting requirement: 66% for Labeling, 50% for Drug Listings, 55% for Establishment Registrations and 66% for Lot Distribution Reports. Less than 25% of respondents use internal systems to prepare these submissions, and of these, only 4% of our respondents have any automated capabilities in place. Preparation of xEVMPD submissions is also an activity which is overwhelmingly handled by point solutions: although just 19% of companies who have an xEVMPD compliance requirement outsource this work, 43% of companies are leveraging the EMA-provided EVWEB online tool to manually submit these records directly into the EMA database. This figure includes, to our surprise, 36% of large companies. Only 15% of these companies have an automated capability in place to generate xEVMPD submissions.

When it comes to upcoming structured data submissions, however, we find that industry is planning to change course. Asked what strategies are included in their approach for upcoming requirements (see figure 10), 69% of our respondents indicated that they plan to establish systems and data governance which will allow them to automatically generate these submissions from their internal systems.

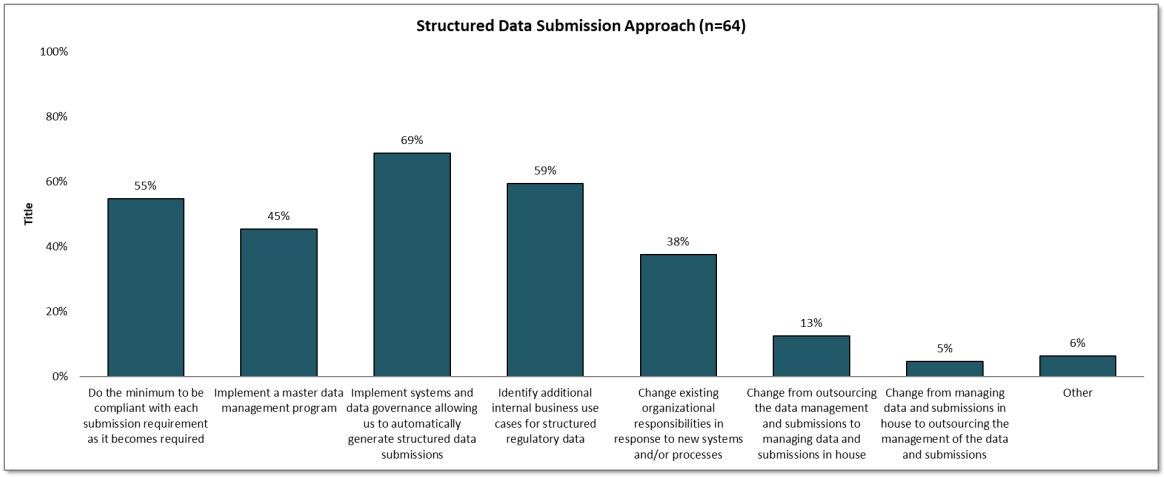
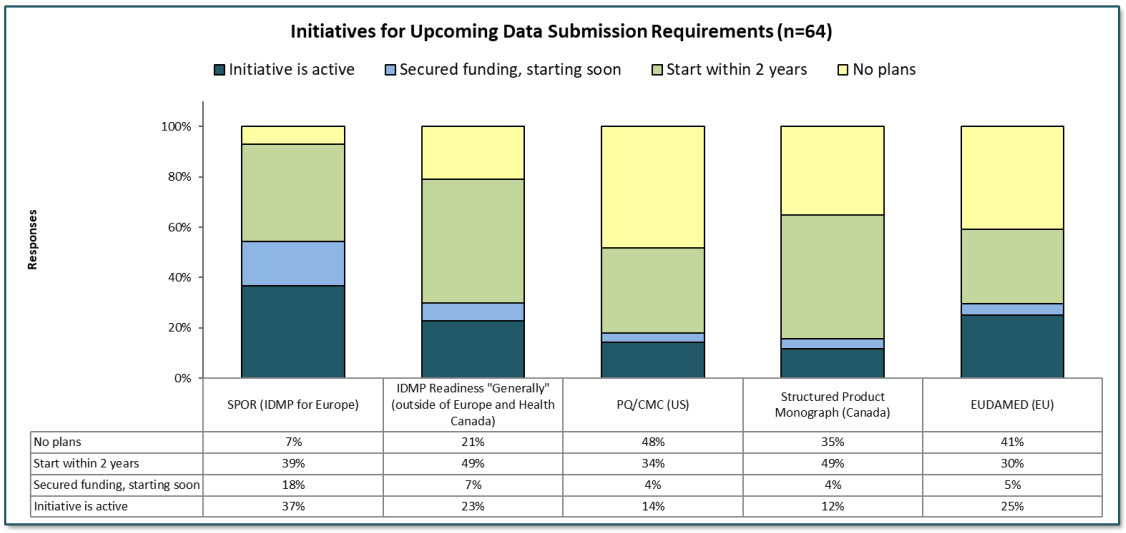


Figure 10: Structured Data Submission Strategy

For our Top Performers, this number is a bit higher, at 73% – and this jumps to an astounding 90% for companies who have already begun planning or executing their preparations for the EU IDMP/SPOR requirement. A high proportion of companies indicate that they also want to leverage this 'submission-ready' data to address additional internal business use cases (59% of all companies and 64% of our top performers have this ambition). These results indicate a significant shift in how regulatory organizations are responding to health authority requirements for data submission. They are no longer seen as tasks to be addressed via point solutions, but rather as catalysts spurring a fresh look at the role of regulatory data in the enterprise. The impact of these ambitions is not yet reflected in data confidence rates for the systems on which companies will rely to provide this data: currently only 42% of companies report high confidence in their product registration data. These confidence levels will need to improve for industry to be successful in achieving the ambition to automatically generate submissions from their systems. This is going to require a paradigm shift in how regulatory organizations look at this data – and a change in approach for the business processes and systems that manage it.

When we look at the tactical plans for implementation, we find industry initiatives to prepare for upcoming structured data submissions are, not surprisingly, focused primarily on the EU IDMP/SPOR requirement (see figure 11). During the early months of 2020, when companies were completing this survey, the European Medicines Agency (EMA) had set expectations that they would be ready to accept initial SPOR product record submissions around the end of 2021, with compliance required by the end of 2022. These timelines were not yet firm and the historical shifting of EMA timelines since 2016 had already resulted in a bit of delay fatigue in many companies. Just 37% of companies who expect to have a SPOR reporting requirement reported an active initiative to prepare for IDMP/SPOR, with another 18% responding that they had secured funding and would be starting their projects soon.



	SPOR (IDMP for Europe)	IDMP Readiness "Generally" (outside of Europe and Health Canada)	PQ/CMC (US)	Structured Product Monograph (Canada)	EUDAMED (EU)
No plans	7%	21%	48%	35%	41%
Start within 2 years	39%	49%	34%	49%	30%
Secured funding, starting soon	18%	7%	4%	4%	5%
Initiative is active	37%	23%	14%	12%	25%

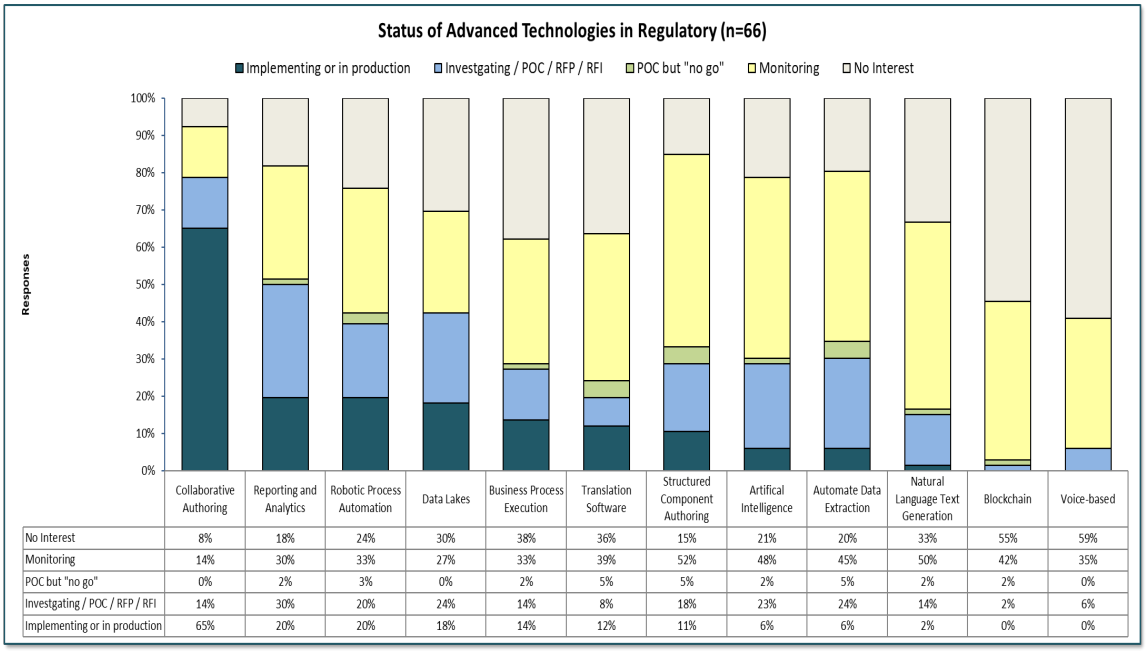
Figure 11: Upcoming Data Submission Status

There is much less activity to prepare for the other structured data submission requirements we asked about in the survey. Just 14% of companies who expect PQ/CMC to apply to them are actively preparing for the anticipated PQ/CMC initiative in the US. This low number is not a surprise; although some unofficial documentation has been published and a limited pilot conducted by FDA they have not yet prepared or issued an official draft guidance. Similarly, Health Canada's Structured Product Monograph (SPM) which is currently in production testing, is expected to be available for voluntary use in 2021, but does not yet have a deadline for mandatory compliance, is shown in our data to be a low priority for most companies. Just 16% of companies for whom this requirement will apply reported an active (12%) or imminent (4%) project to prepare for SPM. EUDAMED, the planned European system for medical device data, had suffered delays and a lack of final functional specifications at the time the survey was conducted, and has also been impacted by a prioritization of some of the more urgent aspects of the overarching Medical Device Regulation (MDR). This has led most companies to postpone initiating work in this area, with just 20% of impacted companies reporting active or imminent projects.

We expected our Top Performers to be proactive, and for Structured Data Submissions they did not disappoint. Seventy-seven percent of the Top Performing companies report having active initiatives to prepare for IDMP/SPOR, in stark contrast to 22% of all other companies. In fact, Top Performers are more active in preparing for all upcoming structured data submissions and are more than twice as likely to be preparing for PQ/CMC (23%/10%) and nearly 4 times as likely to be preparing for Health Canada's SPM (23%/6%). Interestingly, while the Top Performers are slightly more likely to report strategies to implement capabilities to automatically generate structured data submission from their systems than everyone else (73% to 68% respectively), this difference is not significant and indicates that this ambition is more than an advanced strategy, it is an overarching industry ambition. Learning from the experience of the early-adopting top performers over the next two years will be valuable for all of industry as we take the first steps towards a new era of submission-ready regulatory data.

Advanced Technology in Regulatory

We have been discussing and anticipating the promise of emerging technology to improve Regulatory Information Management (RIM) systems for the last few years. This year's research included an examination of current and projected use of emerging technologies and RIM use cases based on advanced technologies. We asked our participants if they were using or planning to use any of a list of technologies or techniques. The results (see figure 12) show that, although adoption is relatively low for all technologies except collaborative authoring, more than 25% of the companies expressed significant interest in most of the listed technologies. Perhaps disappointing to some is that the highest adoption was collaborative authoring, which few would consider an advanced technology. Companies also identified "Improved productivity or efficiency" and "Improved user satisfaction" as the 2 most often cited benefits achieved by companies using any of these technologies for at least 6 months.



	Collaborative Authoring	Reporting and Analytics	Robotic Process Automation	Data Lakes	Business Process Execution	Translation Software	Structured Component Authoring	Artifical Intelligence	Automate Data Extraction	Natural Language Text Generation	Blockchain	Voice-based
No Interest	8%	18%	24%	30%	38%	36%	15%	21%	20%	33%	55%	59%
Monitoring	14%	30%	33%	27%	33%	39%	52%	48%	45%	50%	42%	35%
POC but "no go"	0%	2%	3%	0%	2%	5%	5%	2%	5%	2%	2%	0%
Investgating / POC / RFP / RFI	14%	30%	20%	24%	14%	8%	18%	23%	24%	14%	2%	6%
Implementing or in production	65%	20%	20%	18%	14%	12%	11%	6%	6%	2%	0%	0%

Figure 12 - Advanced Technology Status

The survey also asked respondents to indicate which emerging technologies they were currently experimenting with or planning to investigate, in terms of use cases. Figure 13 shows which use cases are of immediate and longer-term interest as opportunities for automation. Most of these use cases are dependent on AI / Natural Language Processing (AI/NLP) capabilities and are likely to continue to mature over the next few years. 33% of survey participants are actively investigating automated document quality checks, 32% intelligent search of past responses to Health Authority responses, and 29% identify changes in health authority regulations. Large companies have an active interest in most of these use cases, whereas most mid-size and small companies are only planning to investigate within 2 years.

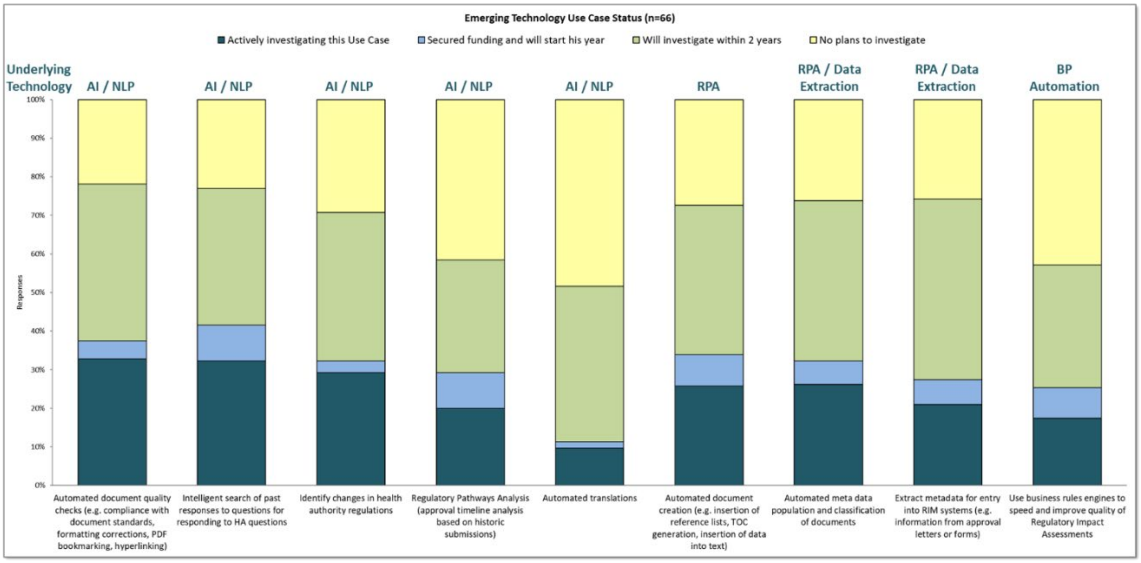


Figure 13 - Emerging Technology Use Cases

In some companies, advanced technologies are being leveraged to automate regulatory activities that require significant manual effort. For example a top 10 bio-pharmaceutical is using the principle "if you can do it by hand, you can automate it" to develop Robotic Process Automation (RPA) tools and to build the RPA tools into existing RIM applications. The promise of data automation can significantly reduce the amount of time spent on routine activities, such as data entry or identifying emails, that should be addressed by regulatory so that regulatory experts can spend more time on more value added work. Especially as regulatory requirements become more complex and regulatory staff are expected to help identify and mitigate potential compliance risks.

We believe that effective use of emerging technologies can benefit both the foundational functions (i.e. improving data quality to promote high data confidence and real time monitoring) as well as more advanced functions of regulatory needs (i.e. predictive analytics). For example, advanced reporting and analytics can identify and report trends in Health Authority questions and concerns and support consistent company responses and corrective actions.

Our data suggests that the adoption of advanced technology use is still in the 'early days' but promises to improve efficiency and performance without increasing regulatory head count. We expect the use of advanced technology and techniques in the next few years to provide significant benefits to regulatory organizations by automating routine information management activities and improving operating efficiency and data quality.

Regulatory Dossier and Content Outsourcing Update

Regulatory dossier outsourcing continues to be a mature capability having both strong provider customer satisfaction levels and more options in the provider landscape. We started to track content (writing) outsourcing in 2020 along with what business benefits participants realized from their outsourcing programs. While we have been tracking dossier outsourcing since 2007 (see figure 14), the last four years have not seen any meaningful change. 2020, however, finds some interesting developments.

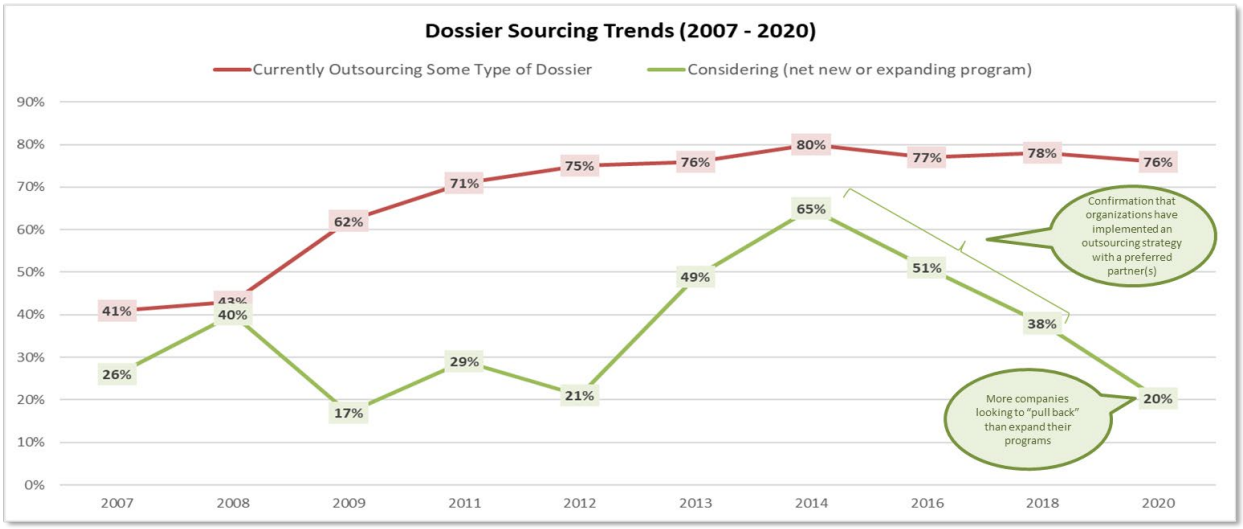
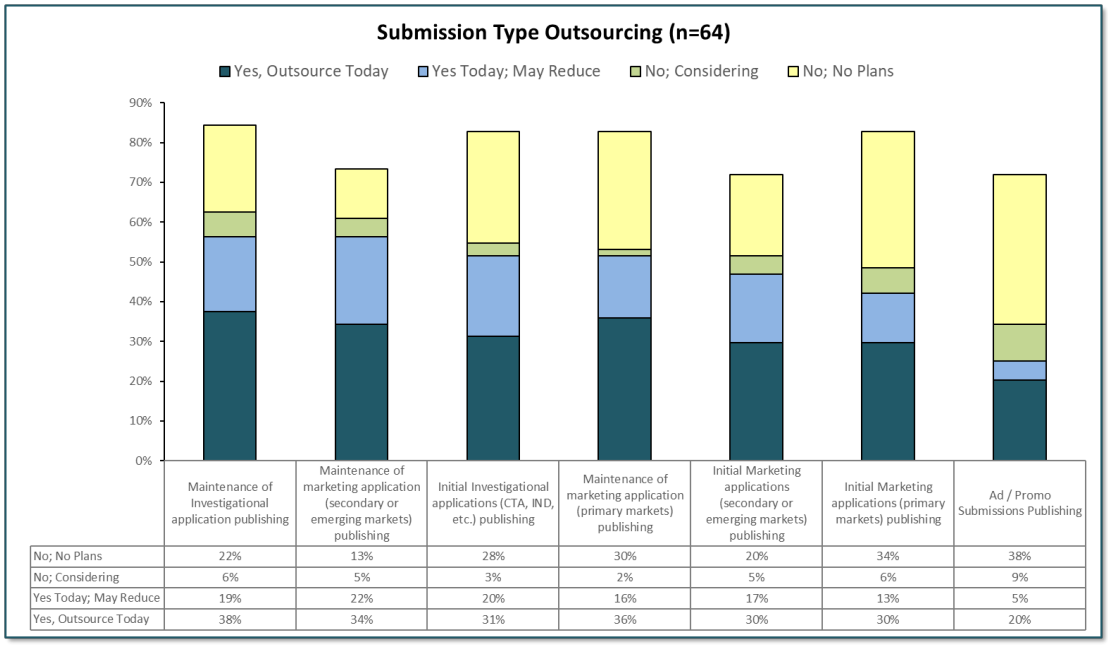


Figure 14: Dossier Outsourcing Trending Summary

What we are keeping an eye on is the potential of a "pull pack" in dossier outsourcing in small and mid-tier companies, but not the large multi-nationals. We must be careful with this data and not draw any conclusions as our 2022 World Class RIM survey will determine if this potential trend emerges or not. Figure 15 provides this year's dossier management outsourcing summary status with the combination of the dark teal (outsourcing today) and the light blue (outsourcing today but may reduce). This potential reduction is primarily from 10 companies and we are following up with these participants. We do have 2 hypotheses to this potential trend:

1. The very small tier typically outsources most or all dossier publishing. At some point, there is a key decision to either continue full outsourcing or start to build some capability internal to support portfolio growth.
2. There is a belief that automation will reduce the cost basis of publishing and doing more in-house may be economically attractive.



	Maintenance of Investigational application publishing	Maintenance of marketing application (secondary or emerging markets) publishing	Initial Investigational applications (CTA, IND, etc.) publishing	Maintenance of marketing application (primary markets) publishing	Initial Marketing applications (secondary or emerging markets) publishing	Initial Marketing applications (primary markets) publishing	Ad / Promo Submissions Publishing
No; No Plans	22%	13%	28%	30%	20%	34%	38%
No; Considering	6%	5%	3%	2%	5%	6%	9%
Yes Today; May Reduce	19%	22%	20%	16%	17%	13%	5%
Yes, Outsource Today	38%	34%	31%	36%	30%	30%	20%

Figure 15: 2020 Dossier Outsourcing by Type

Business drivers for outsourcing programs are identical to 2018 with the top 3 priorities being organizational flexibility to managing spikes in submission volume (75%), increase the efficiency of our operation (64%), static headcount - supplement with contractors and outsource partners (63%).

We asked for the first time about business benefit realization and expected a positive picture. Figure 16 provides the three type of benefits (quality, cost, efficiency) that we tested in the survey. Overall, most participants found the same or higher dossier quality, improved efficiency, and mixed results with cost (increased or reduced). The Top Performers had higher levels of business benefits and better provider satisfaction levels than everybody else. We think this is due to better process maturity and key performance indicator usage.

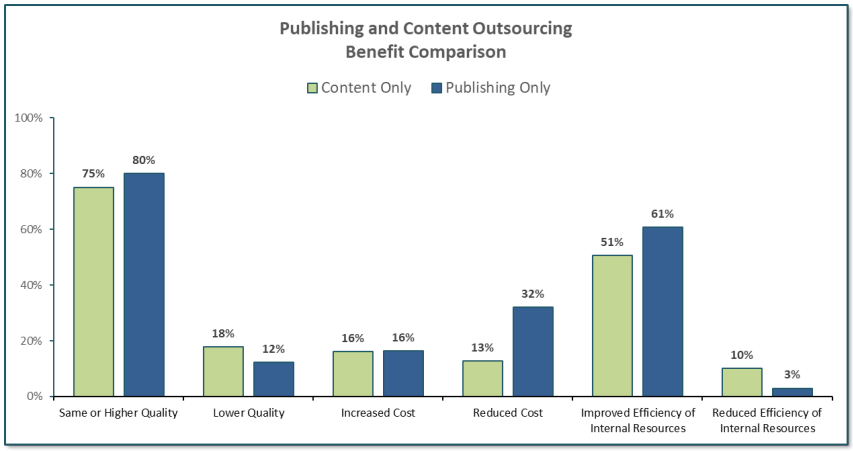


Figure 16: Outsourcing Business Benefit Levels

Finally, we continue to track regulatory operations geographic shifts and only see minor changes with expected expansion in China (15%), North America (12%), Western Europe (11%), Japan (9%) and India / Other Asia Pac (7%). Our detailed service provider landscape report containing dossier and content outsourcing by tier, service provider satisfaction and market share, and total addressable market analysis is in our Executive Lounge (EL) for Premier and EL Content Access Members.

Software Provider Landscape: Key Trends and Provider Update

The software landscape is going through a major transition driven by both technology and business factors. Figure 17 illustrates the combination of data standards, connectivity of RIM into the enterprise, and the acceleration of digitization due to COVID-19 pandemic as major change drivers. The survey also identified cross-functional process optimization as a key investment for 60% of participants, the reduction of operational complexity being the greatest business benefit achieved since our 2018 study, and a shift in system strategy.

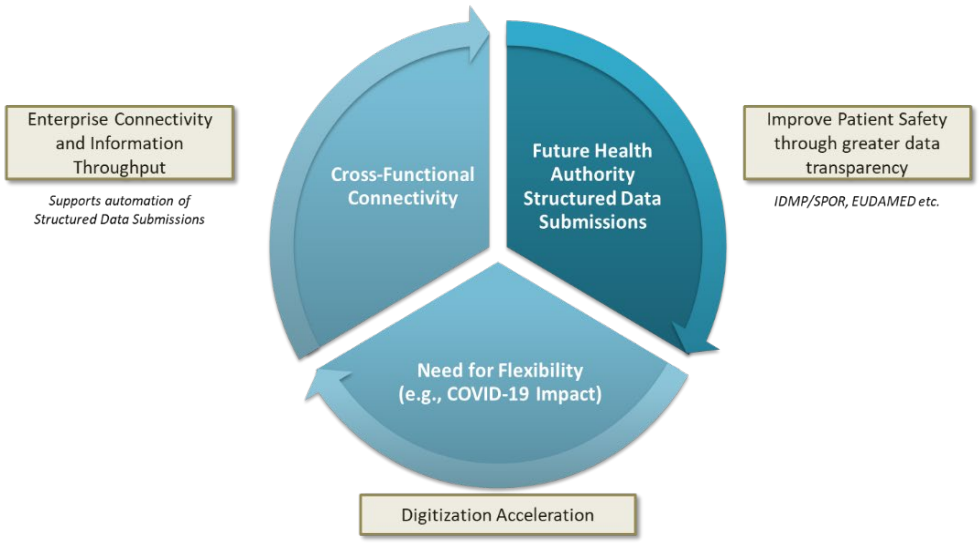


Figure 17: Key Technology Drivers

Since we introduced the concept of an "end to end RIM" approach in 2016, we have been closely tracking both the provider software strategy positioning and industry system strategy preference (platform versus a simplified best of breed) approach. Regardless of strategy option, the clear direction is "simplification" at both the process and system layer.

We asked 2020 participants a more detailed question regarding their system strategy to get a sense of who was "highly likely" or "likely" to progress to a single platform for most RIM capabilities versus a simplified, but connected, partner or traditional best of breed strategy. In 2018, 74% aspired for an "end to end RIM" approach which did not clearly specify the system strategy approach. We see 50% – 60% of the market going with a single platform strategy for most RIM capabilities over the next 3 years. The table below highlights mixed results. There is a slight preference (56%) by study participants for a single platform for most RIM capabilities while the preference for our study Top Performers is "simplified with multiple connected partners" at 69%. Please note, the system strategy question was "check all that apply" which results in the sum of all percentages not equaling 100%.

Population	Number	Highly Likely			
		E2E on Single Platform	Start E2E and may go to a full platform	Simplified with multiple connected partners	Traditional Best of Breed
All	64	45%	11%	28%	14%
Top Performers	13	38%	0%	46%	23%

Industry 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. This is particularly true for those providers who serve the medical device community as our design history file samples are small.

We see three categories of software providers (see figure 18) today and have our summary view of individual providers below.

Platform (most base capabilities)
Amplexor
Ennov
PhlexGlobal (acquired Cunesoft)
Veeva

Hybrid / Emerging Platform
ArisGlobal
Generis
IQVIA

Best of Breed Connected
DXC Technology
Extedo
LORENZ
OpenText / Documentum
PAREXEL
Sparta Systems

Figure 18: Software Provider Categories

Platform Players - This cohort has most of the 15 RIM capabilities in their platform. While most claim to have a credible publishing and label compliance tracking capability, 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 in which no provider has a mature or innovative solution to date.

Amplexor has most of these RIM capabilities today in a holistic platform that embraces a "data driven content management and process automation" architecture. They announced a label management solution in 2018 and have successfully brought this to market along with a new data visualization and analytics capability. They offer both an on-premise and off-premise architecture option and continue to have good satisfaction and innovation index ratings. They have an additional focus on the compliance needs of emerging markets (e.g. EAEU electronic submission) and invested in the RIM & QMS connection for regulatory impact assessments and the change control process. Amplexor has a leading language services division which makes a future translation automation capability interesting from a regulatory operations standpoint.

Ennov has most RIM capabilities along with solutions for clinical, quality, and safety/PV. They continue to have strong innovation and customer satisfaction ratings. While their client base has traditionally been from the small and very small markets, they have successfully graduated into the mid-tier market with several key wins over the past 2 years. They have "caught-up" to others with their xEVMPD module and are IDMP ready with a process-oriented approach allowing for automation. Their solution is built to be very flexible with a strong user interface strategy and are starting to bring some advanced data visualization and analytics to the market. They continue to invest in their organization to support both geographic growth and larger clients with complex product portfolios.

Phlexglobal, who acquired **Cunesoft** this year, is positioned to accelerate investments in their product suite and is well suited to demonstrate leadership with the critical Regulatory and Clinical (PhlexTMF) connection (process, content, and data). They continue to have high innovation index ratings and have made progress with their PhlexDistiller tool (automate data extraction). Their initial clients were in the very small and small tiers and they are starting to progress to large clients with their PhlexRIM suite and all tiers with their PhlexDistiller product.

Veeva is progressing their E2E RIM platform "unified and connected" approach and have gained solid market share in all tiers since 2018. They continue their high regulatory customer satisfaction (ranked #2) and innovation (ranked #1) ratings with significant growth in the regulatory, clinical, quality and safety areas. Veeva is rapidly gaining implementation experience and knowledge with newer capabilities including registration management, publishing and submission planning and management. They have expanded their support to address device, animal health, consumer product and chemical (including crop science) sectors.

Hybrid / Emerging Platforms Players - This cohort has traditional "best of breed" base in either the content or data side of RIM and are trying to expand their solution to encompass most RIM capabilities.

Generis is a long-standing content management player with continued strong customer satisfaction and innovation index ratings. They are greatly expanding their capabilities to include the "data" side of RIM as part of the CARA Life Science Platform (registration management, submission / label plan and track, health authority commitment tracking and the Q&A process). They have invested heavily in label management recently and other adjacent functions such as safety, clinical, and quality. While late-comers to the IDMP conversation, they are bringing a potentially different approach to this complex challenge. Generis market share remains strong and slightly increased during the ongoing Veeva / OpenText content management market battle.

IQVIA purchased many regulatory product and service providers (Acuta, Wingspan, Pilgrim, Highpoint) in 2016 through 2018. They also have access to advanced analytics capability through IMS Health. They have streamlined these different products into an E2E RIM solution set and have strong regulatory services through the acquisition of Quintiles. They are actively pursuing a regulatory intelligence capability that should combine the best of their software and services organizations.

ArisGlobal new LifeSphere® RIMS platform brings an end-to-end regulatory information management approach in the cloud. This include most RIM capabilities except for Publishing and Regulatory Intelligence. They have deep registration and health authority commitment management experience based on 15 years of market experience. Their organization is also very strong in safety / PV, bringing strength to the RIM connection with Safety / PV and ERP.

Best of Breed Connected - This cohort has strengths in a much smaller subset of what we consider E2E RIM and may be impacted with the projected E2E RIM adoption trend in the 2020 – 2022 timeframe.

DXC Technology (formally CSC – FCG/ISI) content management and publishing market share continues to erode; however, their customer satisfaction and innovation index scores have stabilized. Our data in our regulatory software provider market report suggest further market share decline in the near-term.

LORENZ is ranked #1 in customer satisfaction for 2020 and has consistently received high customer satisfaction ratings over the past 10 years. They are now the market leader in publishing solutions where they have gained market share since 2018. The U.S. Food and Drug Administration (USFDA) is now using their docuBridge and eValidator solutions to process incoming and legacy submissions. They also support and work with many other global health authorities and with the projected acceleration of e-submission infrastructure from the COVID-19 pandemic; we believe this will greatly benefit LORENZ.

Extedo is a traditional publishing provider that supports both industry and the global health authorities. They recently expanded their solution set to take an E2E RIM approach for most RIM capabilities along with support for IDMP. They have emerged in the safety space with very small and small tier customers and have built a small regulatory publishing services division. We believe this diversification will be critical for Extedo long-term health.

Intagras is a label compliance tracking capability built to support a critical compliance challenge with most mid-tier and large companies. While their market share has incremental growth, they have not been able to "breakout" to market leadership. They may be at risk long term if the E2E RIM platform players are able to satisfy core label content management and label compliance tracking requirements in their core platforms.

PAREXEL is still the market leader in registration management for the large and mid-tier and has market leadership with their publishing solution. They are catching up to competitors with their SaaS/Cloud offering and are converting many long-standing clients to this architecture. They continue to invest in data visualization methods to better support dashboards based on a very comprehensive data model built on decades of experience. We believe PAREXEL will make the SaaS/Cloud transition and continue to be strong and relevant in the near-term.

Sparta Systems is a strong QMS provider that has had mixed results with their registration management and label tracking capability based on our customer satisfaction and innovation index data. Their strength is QMS which is one important RIM connection point, but their market share has declined since 2018 and our 2020 data suggest further decline is expected.

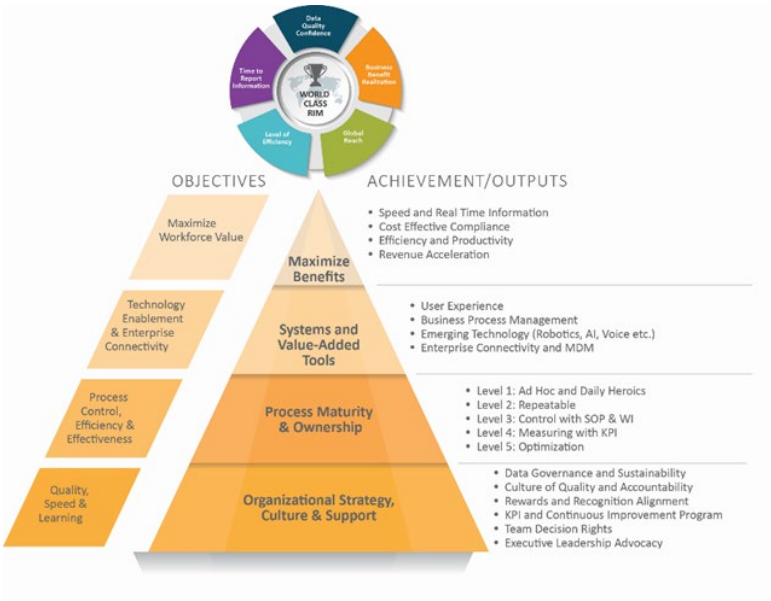
Finally, figure 19 depicts the current market share leaders by tier with the bold font highlighting those providers who increased their market share standing when compared to 2018. Please note, we track Microsoft Office products (Excel and SharePoint) as they be the primary tool, however this is quickly changing.

Solution Type	Large Tier (n = 15)	Mid Tier (n = 23)	Small Tier (n = 28)
Submission Content Management	1) OpenText - Documentum **2) Generis / Veeva** 3) DXC FirstDoc	**1) Veeva** 2) OpenText -Documentum 3) DXC FirstDoc	1) Veeva **2) SharePoint** 3) OpenText - Documentum
Publishing	1) PAREXEL **2) LORENZ** 3) DXC eCTDExpress	**1) LORENZ** / PAREXEL 2) DXC /**Extedo**	1) LORENZ 2) Extedo 3) IQVIA (Acuta)
Product Registration	1) PAREXEL 2) Custom 3) ArisGlobal	1) PAREXEL 2) Custom **3) ArisGlobal** or Excel	**1) Veeva** 2) Excel
Submission Forecasting and Planning	1) Custom 2) Excel 3) PAREXEL / SharePoint	1) SharePoint 2) Excel	**1) Veeva** 2) Excel **3) SharePoint**
Label Tracking	1) Custom 2) Intagras or PAREXEL	1) Custom **2) Sparta** 3) PAREXEL / **Intagras**	1) Custom / Veeva **2) Intagras** / Sparta
HA Interactions	1) Custom 2) OpenText -Documentum, SharePoint, DXC, PAREXEL	1) SharePoint 2) Excel 3) Veeva	**1) Veeva** 2) Excel

Figure 19: Market Leaders by Size of Company Summary (May 2020)

STUDY CONCLUSION

We wish to leave you with several themes as you make progress on your or your clients RIM performance journey:

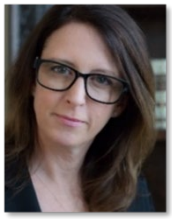


1) Top performance is derived from excellence in the organizational elements and "global" process maturity. This foundation allows an organization to maximize their technology investments.
2) A culture of quality is critical to long term data quality confidence and needs to be supported by rewards and recognition systems.
3) System and process simplification is critical for infrequent users and to support RIM connectivity to other key functions.
4) 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 the survey co-founder with the first industry survey conducted in 2007. The 2020 World Class RIM follow-up will be the 35th survey conducted under Steve's leadership. He has over 30 years of business experience with the majority in the biopharmaceutical and healthcare industries. His early career was spent at Johnson and Johnson and then moved into consulting where he managed 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 facilitating strategic change. He consults with all sized companies and those that are growing and scaling. He has a Master of Science in Organization Development from American University with distinction for his field work and a BS in Business Computer Science. Steve is a frequent speaker and was named to the 2017 PharmaVoice 100 entrepreneur category for his contributions to industry.



Kelly Hnat of K2 Consulting (new to the core research team) has over 25 years' experience in the pharmaceutical industry leading both IT and RIM/Reg Ops organizations in several companies, including Wyeth, Pfizer, Shire and Teva. She is a key industry leader in the EU implementation of IDMP as a member of the SPOR Task Force and its PMS sub team and is a member of ISO TC/215. Kelly is President of IRISS (www.iriss-forum.org) and is on the leadership

Greg Brolund (survey team since 2009) is a Global Pharma management and technology consultant with extensive experience in business processes and supporting IT for product labeling, submission publishing, global Health Authority interactions, and pharmacovigilance programs. He served as the Rapporteur of the ICH M2 Working Group Rapporteur from 1998 through 2002 for the development of the initial production version of the eCTD and the implementation of the E2B ICSR electronic submission. He has 25 years of experience with the FDA leading development of FDA's internal IT systems in support of the CDER and CBER submission review process. After leaving the FDA, he served as the US HHS CTO and was a pharmaceutical industry consultant with Booz Allen Hamilton. He holds a Master of Chemistry degree from the American University in Washington DC.

Sarah Powell (survey team since 2015) is the President of Powell Regulatory Services. Sarah has over 30 years of experience in the life sciences industry (Clinical, Quality Control, Regulatory Affairs and Regulatory Operations). In the past 16 years as a consultant, she has assisted clients with regulatory process improvements, standards development, defining filing strategies and writing and review of submission content. She has extensive experience with projects related to design and implementation of regulatory solutions including document management, submission planning, publishing, and registration management. Sarah is a past executive at Chiron, First Consulting Group and PAREXEL. She holds a Bachelor of Science degree in Nutrition Science from the University of California, Davis, is

team for IRISS' IDMP Topic Group. Her company, K2 Consulting (www.k2rim.com), is a specialty firm focused on Regulatory Affairs and a partner of Gens and Associates.

Katherine Yang-Iott is a core member of the Gens and Associates team with over 15 years of experience in the healthcare and pharmaceutical industry leading and managing complex interdisciplinary projects. She worked as a research scientist at Regeneron Pharmaceuticals and The Children's Hospital of Philadelphia before transitioning to consulting work, where she focused on strategy development and continuous improvement projects to support research operations. Katherine has a Master of Science in Organizational Dynamics from the University of Pennsylvania and a Bachelor of Science in Biochemistry.

Regulatory Affairs Certified in the US and EU, and a RAPS 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, QC, 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 & Compliance Tracking)
11) **Reporting, Analytics, Dashboard**
12) **Data Standards and Governance Management**
13) **Design History File – Medical Device**
14) **Regulatory Intelligence**
15) **Ad / Promo**

10 Connection Points

1. **Product Change Control Process**
2. **Product Supply Release**
3. **Clinical (eTMF)**
4. **Clinical Trial Tracking (CTMS)**
5. **Label Artwork Management**
6. **Enterprise Portfolio Management**
7. **PLM** (typically Medical Device)
8. **Master Data Management**
9. **Data Lake** (pooling from multiple systems)
10. **Safety / PV**

PROVIDERS IN INNOVATION RATING (SORTED ALPHABETICALLY)

1. Amplexor
2. ArisGlobal
3. DXC Technology (CSC - includes former ISI / FCG)
4. Ennov
5. Extedo
6. Generis
7. Globalvision
8. I4i
9. Instem
10. Intagras
11. IQVIA (includes Acuta)
12. LORENZ
13. Microsoft
14. OpenText (Documentum)
15. Oracle
16. Orion (includes Cabeus)
17. PAREXEL (includes former Liquent)
18. PhlexGlobal (includes Cunesoft)
19. PTC
20. Schlafender Has (TVT)
21. Sparta
22. Veeva

GENS AND ASSOCIATES INC. BENCHMARK HISTORY

1) **2007 *eCTD/Electronic Document Management Survey,* (with ILSS)**
2) 2007 *Promotional Material Process Metric*
3) 2007 *Labeling Pulse Survey*
4) 2008 *eCTD and Organizational Implications*
5) 2008 *Labeling Best Practices Survey*
6) 2008 *Regulatory Core Dossier Submission Strategy*
7) **2009 *Electronic Document Management/Collaboration* (with ILSS)**
8) 2009 *Industry Engagement*
9) 2009 *Regulatory Submission Management and Production Planning*
10) 2010 *Global Pharmaceutical Regulatory Affiliate Strategy*
11) 2010 *Regulatory Information Management & Health Authority Trends*
12) 2010 *Vendor Market Share Update*
13) **2011 *Collaboration and Content Management Trends* (with ILSS)**
14) 2011 *Regulatory Futures*
15) 2011 *Publishing and Dossier Management (organization and outsourcing)*
16) 2011 *Labeling and Promotional Material Organization Strategy*
17) 2012 *Regulatory Information Management Trends*
18) 2012 *Vendor Market Share Update*
19) **2013 *Managing Regulatory Information as a Corporate Asset (n = 37)***
20) 2013 *Regulatory Operations Pulse*
21) 2013 *CTA Pulse*
22) 2013 *EDMS and Digital Archive: One in the same?*
23) 2014 *Regulatory IT Resource Pulse*
24) **2014 *Next Generation RIM and Regulatory Intelligence: Strategy, Investments, and Status (n = 41)***
25) 2015 *Product Registration Investment Pulse*
26) 2015 *Next Generation Content Management (n = 21)*
27) 2015 *Addressable Market update (solution and services)*
28) 2015 *Legacy Product Outsourcing Pulse Survey*
29) **2016 *Pursuing World Class RIM: Strategy, Measures, and Priorities (n = 54)***
30) 2016 *Enterprise Content Management Governance Structure Pulse Survey*
31) 2017 *Safety Systems Trends: Innovation, Operating Model and Growing TCO Pulse (n = 17)*
32) 2017 *Regulatory Services and Software Addressable Market Analysis Update (top 500)*
33) **2018 *Pursuing World Class RIM: Connections to QMS, Supply Release and Product Change (n = 72)***
34) 2018 *Submission Content Management Capability Change Investment Pulse (n = 10) – Top 30*
35) **2020 World Class RIM: IS Industry at a Performance Tipping Point *(n = 70)***
36) 2020 COVID-19 Regulatory Impact Pulse Survey (*n = 245) – Individual Response Survey*