2022 Regulatory Intelligence Industry and Software Provider Pulse Survey Summary

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GENS & ASSOCIATES

Introduction

We conducted our first dedicated Regulatory Intelligence (RI) pulse survey in 2018 and regularly include basic RI capability questions concerning efficiency, automation goals, and global reach in our World Class Regulatory Information Management (RIM) survey series (2016, 2018, 2020, 2022).

As a follow-up to the 2018 baseline study, we focused this fall 2022 study on how companies collect, curate, and distribute regulatory intelligence information; their approach or planned approach to automating these activities; and their approach to integrating RI into regulatory systems and processes. The following are key study takeaways:

- **RI organizations have a broad remit with constrained resources** – No common organizational structure or strategy was found. 57% cited more resources as a top need while 50% viewed automation as a top priority. Most are constrained by limited resources outside of the North American and European markets.
- **Potential automation opportunities are in an early stage of maturity** – Most are using manual methods but are highly interested in automation opportunities. Solution vendors are investing in RI management capabilities but have not reached a stage of maturity, in our opinion. Many solution venders have basic automation in their product roadmaps.
- **RI Management is generally effective, but very manual** – We found it interesting that 60% had limited key performance indicators (KPIs), mostly focused on RI service satisfaction and internal request volume while 40% had no KPIs. Our 2022 World Class RIM survey (n = 76) found an overall industry efficiency average for RI of 48%, which supports our conclusion that while RI information management is “effective”, it is often inefficient with automation being an attractive option.
- **Subject Matter Expert Networks (SME) tend to be underutilized** – While 55% of respondents find their SME Networks effective, it was clear from the data that large and mid-tier companies engage and manage their SME networks more effectively than smaller companies.

The information and graphs herein are based on the 2022 Regulatory Intelligence Pulse survey results, client work, and our insights. The paper’s structure is as follows:

- Study Background
- Regulatory Intelligence Model and Department Remit
- Automating Regulatory Intelligence Management Activities
- Performance of Regulatory Intelligence Departments
- Measuring Performance
- Conclusion

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

Steve Gens

Greg Brolund

Study Background

The study was designed in the summer of 2022 and went through 3 design sessions with both industry and software provider representation. The study opened in September and closed in November 2022. As part of the research process, we also submitted a questionnaire to 15 software providers, of which 14 responded with information about their regulatory intelligence management capabilities.

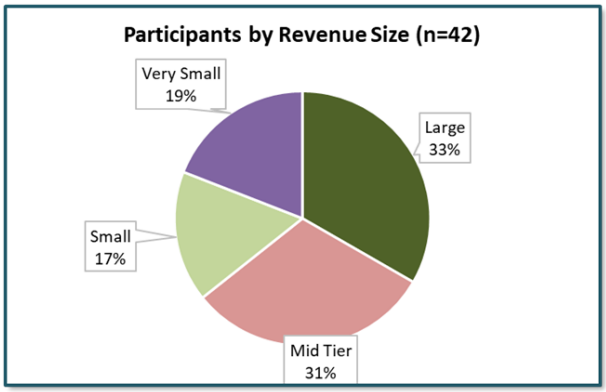


Figure 1 - Responses by Size of Revenue

The study enrolled 42 life science companies. These companies represent the biopharmaceutical, medical device, and consumer product sectors. They range in size (by revenue) from large multinationals to very small (clinical stage). Figure 1 shows the distribution by revenue of the 42 participating companies. The responses were nearly evenly divided between European and United States headquartered companies, with an additional 4 companies headquartered in Japan.

Regulatory Intelligence Model and Department Remit

For this study we describe the high-level operating model for Regulatory Intelligence departments as depicted in Figure 2 and collected data on each activity effectiveness and automation status. In this model, the key functions are collection, analysis, and distribution of (RI) information. Contributors and consumers include both internal and external sources and stakeholders.

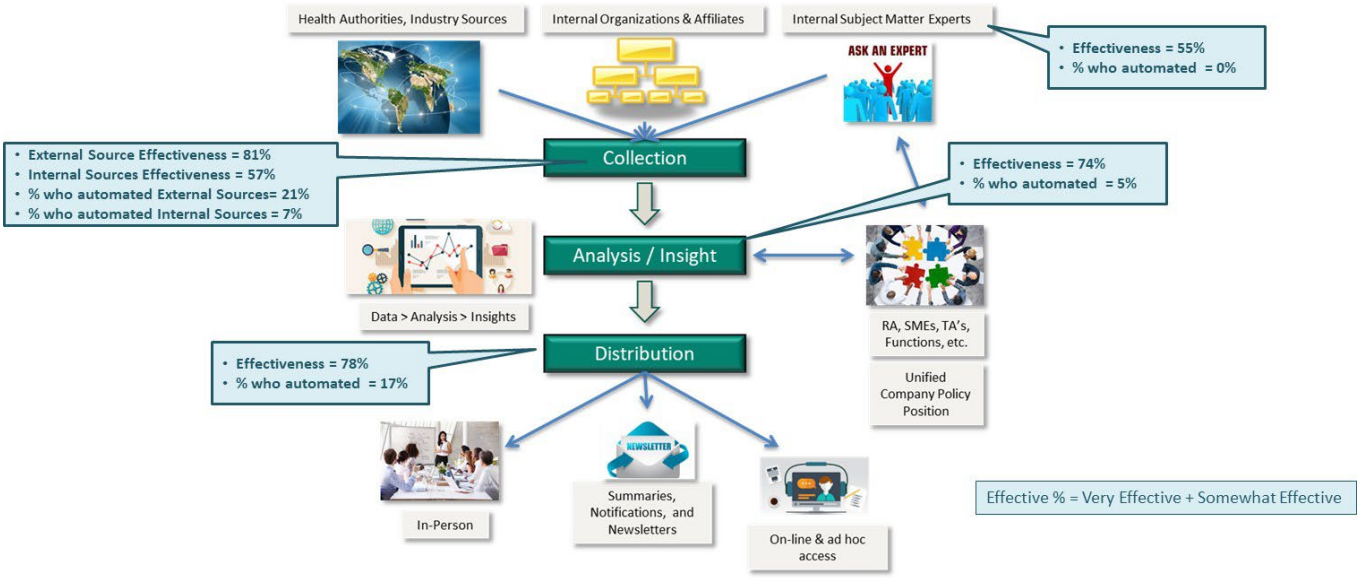


Figure 2 - RI Management Model

In the past, we observed that RI departments generally have broad remits and relatively small, dedicated staff. To determine if this is still the case, we provided a list of 15 typical RI management activities to determine the current breadth of the remit for typical RI departments.

Each company was asked to identify the level of importance of each activity or service. Table 1 shows the percentage of companies indicating either "Very Important" or "Somewhat Important" for each activity.

Activities Provided by the Regulatory Intelligence Department	Percent of Companies Indicating This Activity is "Important"
Identify new or changed regulatory guidance, legislation, or policies from Health Authorities	93%
Analyze and interpret new or changed regulatory guidance, legislation, or policies from Health Authorities	88%
Provide and facilitate access to regulatory intelligence from external, commercially available sources (e.g., Cortellis)	86%
Provide regulatory research on specific topics by request (e.g., Health Authority precedence, local market requirements)	83%
Participate or coordinate participation in external industry / Health Authority working groups to influence changes in regulatory guidance, legislation, or policies	81%
Provide a collection of tools and information sources to help develop regulatory strategies (e.g., internal / external searchable database)	81%
Provide regulatory policy interpretation regarding therapeutic areas and products	79%
Support and facilitate your company's response / comments to Industry Associations and/or Health Authorities regarding proposed new or changed regulatory guidance or legislation	79%
Build and manage a network of Subject Matter Experts across the organization	79%
Provide or facilitate internal trainings on emerging regulatory topics	76%
Support (but not lead) impact assessment collaboration with relevant stakeholders to determine impact on your company's business and work practices	74%
Provide regulatory intelligence from internal experience, lessons learned, etc.	74%
Support regulatory strategy development	71%
Build and manage a database of regulatory information not available through commercially available sources	69%
Lead impact assessment collaboration with relevant stakeholders to determine impact on your company's business and work practices	64%
Provide competitive intelligence (i.e., your competitor's submissions, status, pipeline, etc.)	45%

Table 1 - Important Regulatory Intelligence Management Activities

It is clear from the data that companies are expecting their RI departments to perform a broad set of activities beyond the traditional tracking and listing of Health Authority regulations and specifications.

Today's RI departments are expected to provide analysis, insights, and impact assessments of current and future Health Authority regulatory requirements. Only "competitive intelligence" was important to less than 50% of participating companies, however, the large tier had 79% reporting the importance of competitive intelligence. We also note that smaller companies are having difficulties satisfying their internal customers; having a broad RI remit with limited resources is a serious constraint.

Automating Regulatory Intelligence Management Activities

One way to maximize the use of available resources to manage RI information is to employ automation for some or all of the activities in the RI department remit. Today, most companies are using manual methods for these activities with low levels of digitization planned (see Figure 3).

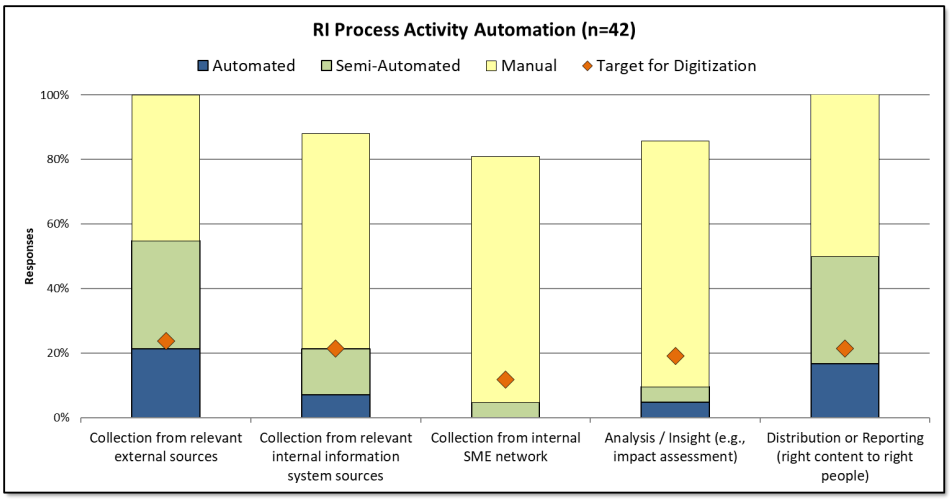


Figure 3 - Automation Status (High Level)

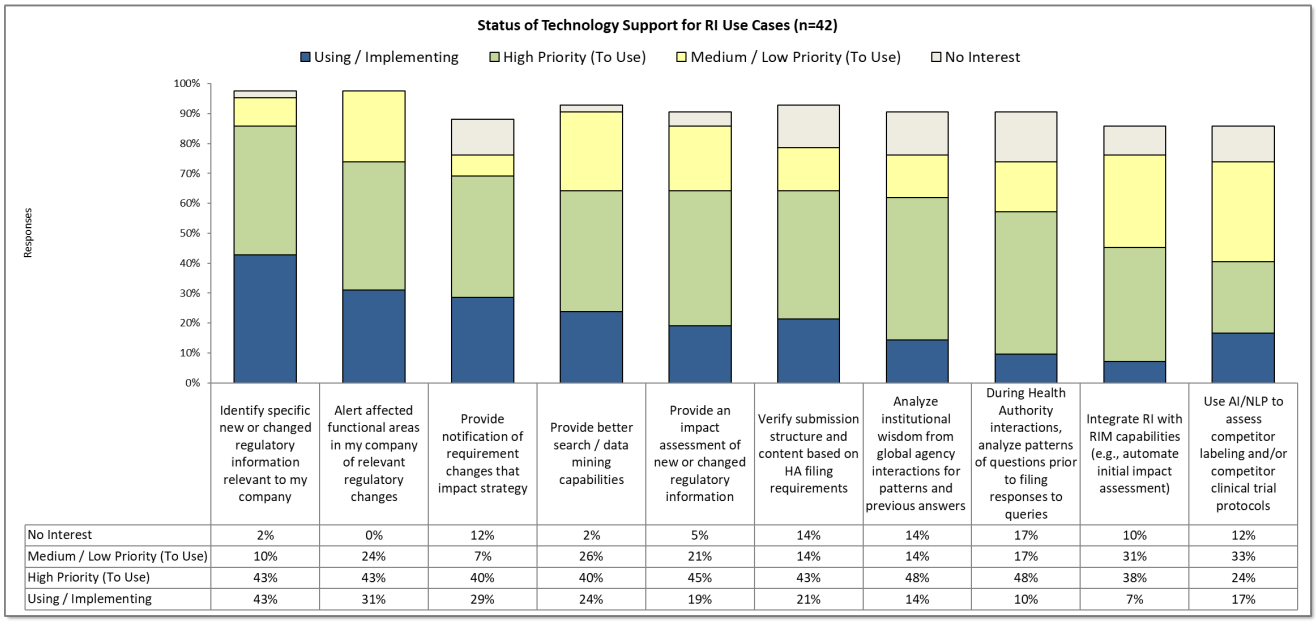
Only two activities, collection from external sources (i.e., commercial providers and Health Authorities) and distribution to stakeholders, were identified as being automated by a significant number of companies (9 companies and 7 companies, respectively). Leveraging internal sources is almost entirely manual and an automation target for very few companies.

Small companies in particular, have very low automation adoption levels and only one small company is targeting any activity for digitization. Mid-tier companies have the highest percentage of automated activities, with 31% automating collection from external sources and 23% providing some level of automation for information distribution or reporting.

Another view of the level of automation is provided by examining the status of technology support being applied to 10 RI management use cases. Figure 4 shows the 10 use cases with the level of technology support currently in place or where there is a priority assigned to providing technology support.

Technology support is broadly defined and ranges from provision of a structured database of regulatory requirements through early efforts to apply natural language processing and artificial intelligence

analysis to databases and documents. It is our assessment that 6 of the 10 use cases would require intelligent analysis of internal and external information from multiple sources. These sources range from structured databases (e.g., country filing requirements) to unstructured documents, including presentations, working group notes and specific experiences documented in a variety of file formats. The primary challenge for these use cases is the availability of complete, authoritative, and reliable structured and unstructured information. Without authoritative sources, technology solutions are ineffective.



	Identify specific new or changed regulatory information relevant to my company	Alert affected functional areas in my company of relevant regulatory changes	Provide notification of requirement changes that impact strategy	Provide better search / data mining capabilities	Provide an impact assessment of new or changed regulatory information	Verify submission structure and content based on HA filing requirements	Analyze institutional wisdom from global agency interactions for patterns and previous answers	During Health Authority interactions, analyze patterns of questions prior to filing responses to queries	Integrate RI with RIM capabilities (e.g., automate initial impact assessment)	Use AI/NLP to assess competitor labeling and/or competitor clinical trial protocols
No Interest	2%	0%	12%	2%	5%	14%	14%	17%	10%	12%
Medium / Low Priority (To Use)	10%	24%	7%	26%	21%	14%	14%	17%	31%	33%
High Priority (To Use)	43%	43%	40%	40%	45%	43%	48%	48%	38%	24%
Using / Implementing	43%	31%	29%	24%	19%	21%	14%	10%	7%	17%

Figure 4 - Technology Support for RI Use Cases

In a blog for Gens & Associates, John Cogan has written about the challenge of automating complex regulatory use cases from an economic and reward/benefit perspective (see blog at: https://gens-associates.com/2022/10/17/automation-and-ai-technology-in-regulatory/). He found that it has been difficult to provide a strong justification to pursue automation projects.

A commonly described RI information analysis use case demonstrates the challenges and complexity in today's environment.

In this example, the goal is to "automatically" **identify** and **analyze the impact** of new or updated regulations from one or more Health Authorities and **notify** the right stakeholders.

This use case is much more than locating and organizing regulatory requirements, submission formats, and the like. There are multiple outcomes implied in this use case that employ aspects of natural language processing and artificial intelligence. For example, Table 2 describes the expected outcomes of the use case and a short list of what would be needed to support automation to achieve each outcome.

Outcome	What Is Needed
Identification of new or updated regulatory requirements from sources that include draft or proposed requirements as well as final published requirements	• Access to relevant laws, regulations, guidance, presentations, and industry and Health Authority working group products
A determination of relevance and **impact** to my company	• Relevance and impact determination requires access to the company's product and marketing information including therapeutic, clinical and CMC for marketed, pending marketing approval, and in clinical trials
Analysis of previous experience or precedents	• Decisions and actions of Health Authorities on related matters • Internal information in a consumable form including Health Authority interactions, internal subject matter expert (SME) assessments, meeting and working group reports, previous company implementation decisions and actions
Alerts to the **right** people	• Defined internal staff roles and responsibilities related to activities likely to be affected by regulatory changes

Table 2 - Sample Use Case

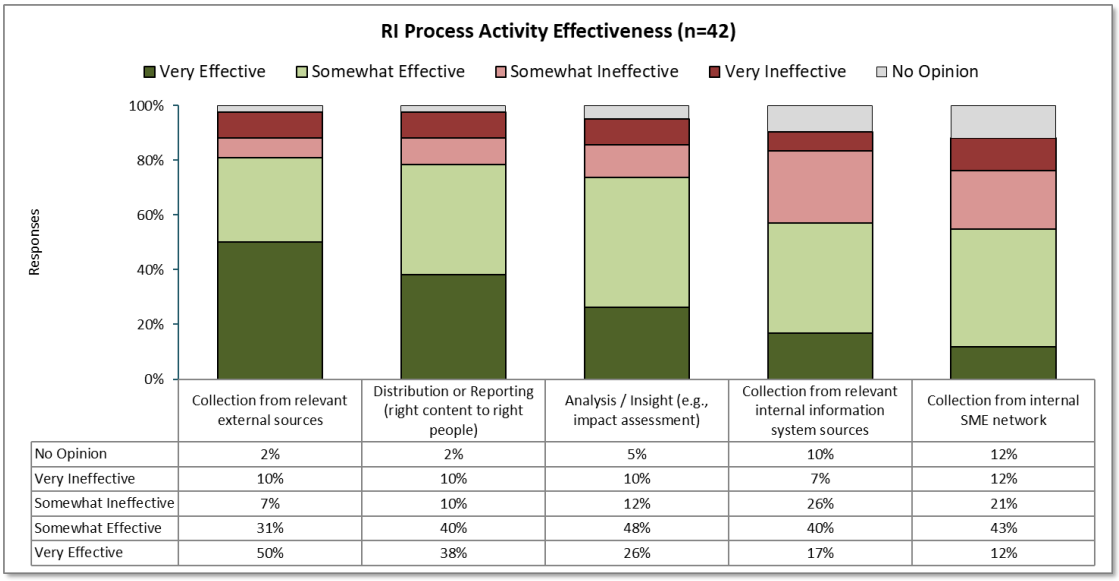
In this case, we believe the outcomes are highly desirable. Additionally, most companies would likely agree that it is highly improbable that the items in the "What Is Needed" column are available or could be available as authoritative sources.

This leads to the conclusion that for the foreseeable future, a more practical approach to "automate" RI information management is to augment human collection and analysis with technology. A simple example is the use of intelligent search techniques of structured and unstructured sources to answer specific questions posed by staff. After an analysis of the results by knowledgeable professionals, supporting technology to notify the right receipts and distribute the results would be used.

This incremental use of technology would improve efficiency while staying within the realm of the practical.

Performance of RI Departments

Given the broad remit, limited resources, and limited automation, the performance in terms of effectiveness of RI departments is remarkably good. As shown in Figure 5, most companies report being effective in basic collection, analysis, and distribution of RI information. Collection from internal, non-Health Authority sources is the most challenging activity. Small companies report being less effective than other companies when collecting information from their SME networks.



	Collection from relevant external sources	Distribution or Reporting (right content to right people)	Analysis / Insight (e.g., impact assessment)	Collection from relevant internal information system sources	Collection from internal SME network
No Opinion	2%	2%	5%	10%	12%
Very Ineffective	10%	10%	10%	7%	12%
Somewhat Ineffective	7%	10%	12%	26%	21%
Somewhat Effective	31%	40%	48%	40%	43%
Very Effective	50%	38%	26%	17%	12%

Figure 5 - RI Process Effectiveness

The survey also included questions that explored effectiveness from additional dimensions. When all of these questions are taken into account, we see in Figure 6 that the majority of companies rate themselves as at least "Somewhat Effective". The orange lines indicate the average effectiveness score for each company size group.

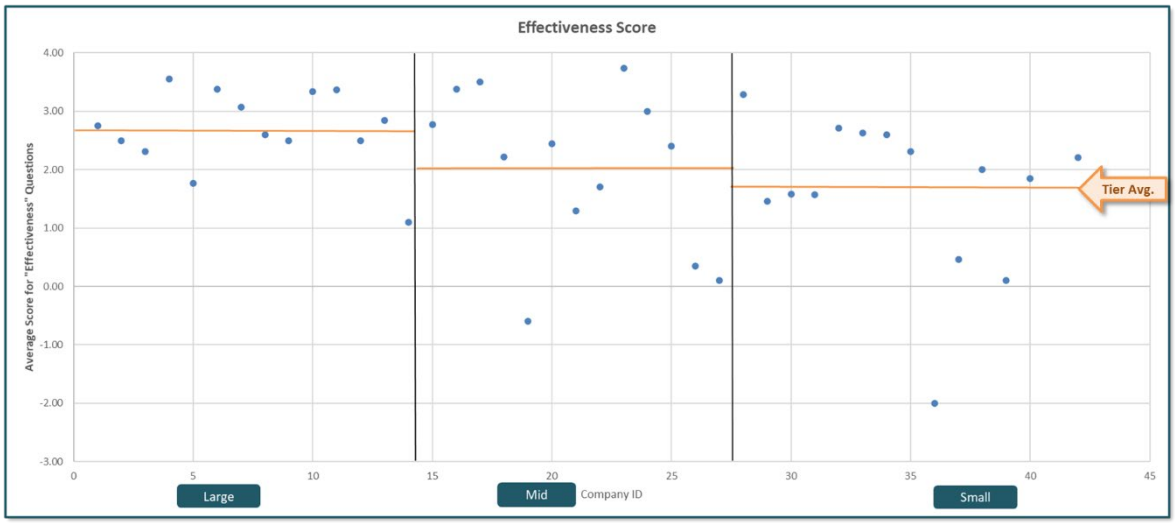


Figure 6 - RI Department Effectiveness Score

Almost all companies in our survey are using multiple tools and techniques to manage RI information as shown in Figure 7. We found no relationship between the number of tools used and reported effectiveness, leading to the conclusion that companies are still in search of an optimum solution.

Figure 7 also shows that large and mid-tier companies use more tools on average than smaller companies.

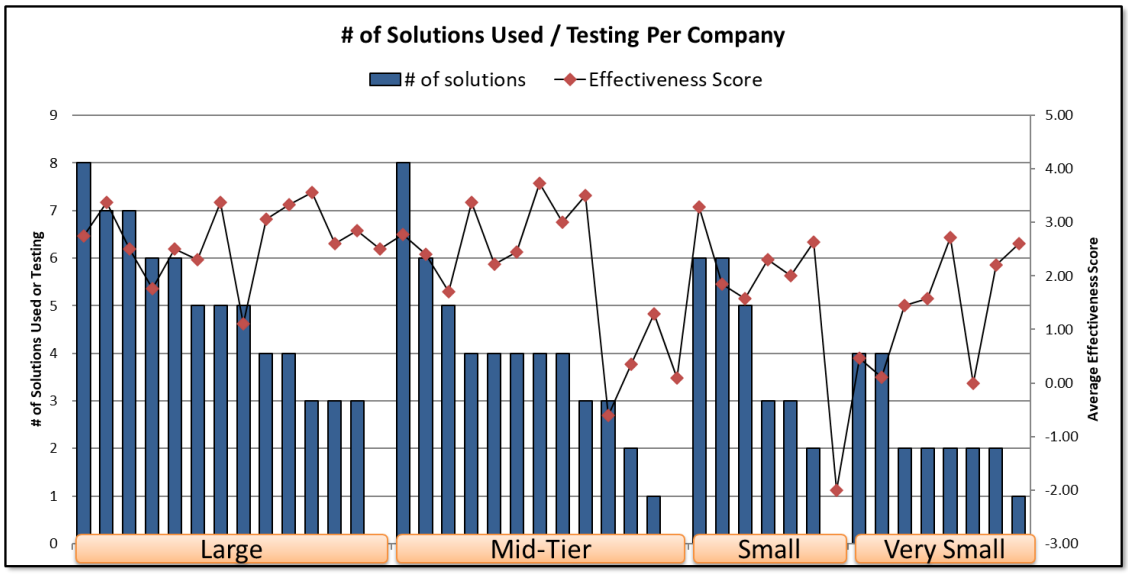


Figure 7 - Number of RI Solutions Used

The unanswered question is whether RI departments can meet customer demands efficiently. As with many regulatory affairs organizations, being effective is required and is often achieved through extraordinary efforts. Efficiency could be increased through improvements such as:

- Better and more automation support
- Better internal processes for utilizing subject matter experts
- Improved access to RI data
- A comprehensive and authoritative source of both "hard" intelligence (e.g., Health Authority requirements) and "soft" intelligence (e.g., internal insights and lessons learned)

Measuring Performance

Improving any organization and its processes is facilitated by having good data on how well the organization is performing. Key Performance Indicators and other metrics are important for understanding how well the organization is performing and knowing what to target as part of a continuous improvement program.

Our survey data suggests that using metrics and KPI to understand and improve RI department performance is very limited in most companies and still maturing in most others. 40% of the companies do not currently have KPI to measure their effectiveness. The most common KPI are shown in Table 3.

Typical KPIs Mentioned	% of Companies With This KPI
Voice of Customer / Satisfaction (Surveys, Polls, etc.)	21%
# of and/or Time to Respond to ad hoc Internal Requests	21%
Advocacy / Comments to HA's, and Trade Groups	10%
# of Impact Assessments Completed	7%
Time to Distribute New Information to Stakeholders	7%
Stakeholder Usage of Information and Tools	5%
Internal Communication (Time and Effectiveness)	5%
Compliance: (# Identified Gaps Resolved Based on RI)	2%
Compliance: Time to Resolve Compliance Gaps	2%

Table 3 – Typical KPI

We believe increased adoption of KPI will help RI departments better understand their strengths and weaknesses and will provide a baseline from which to evaluate the success of automation projects, process and data improvements, and organization changes.

Study Conclusions

In our view, RI departments:

1) Are tasked with a broad, global remit while continuing to be resource constrained
2) Are performing effectively but are generally inefficient
3) Would benefit from improved use of their SME network, especially in the smaller companies
4) Should continue to explore "practical" automation projects that could lead to more extensive artificial intelligence capabilities in the future

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.

Greg Brolund (Study Lead) 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.

Software Provider Reviewed

Study participants received the detailed data from our software provider questionnaire. While we provided a summary of the data received as part of the study, we did not verify (via demonstrations) each individual software provider's claims regarding their RI capability. The providers included are:

1) Amplexor
2) ArisGlobal
3) Clarivate
4) Deloitte
5) Ennov
6) Extedo
7) Freyr Solutions
8) Generis
9) Indegene
10) IQVIA
11) Orion
12) Phlexglobal
13) RegDesk
14) Rimsys

Gens & Associates Inc. Recent Benchmark History

1) 2014 *Next Generation RIM and Regulatory Intelligence: Strategy, Investments, and Status (n = 41)*
2) 2015 *Product Registration Investment Pulse*
3) 2015 *Next Generation Content Management (n = 21)*
4) 2015 *Addressable Market update (solution and services)*
5) 2015 *Legacy Product Outsourcing Pulse Survey*
6) 2016 *Pursuing World Class RIM: Strategy, Measures, and Priorities (n = 54)*
7) 2016 *Enterprise Content Management Governance Structure Pulse Survey*
8) 2017 *Safety Systems Trends: Innovation, Operating Model and Growing TCO Pulse (n = 17)*
9) 2017 *Regulatory Services and Software Addressable Market Analysis Update (top 500)*
10) 2018 *Pursuing World Class RIM: Connections to QMS, Supply Release and Product Change (n = 72)*
11) 2018 *Submission Content Management Capability Change Investment Pulse (n = 10) – Top 30*
12) 2020 *World Class RIM: IS Industry at a Performance Tipping Point (n = 70)*
13) 2020 *COVID-19 Regulatory Impact Pulse Survey (n = 245) – Individual Response Survey*
14) 2021 *Structure Content Authoring (n = 25) Pulse Survey*
15) 2021 *IDMP/SPOR Architecture Pulse Survey and Software Provider Review*
16) 2022 *World Class RIM: Accelerating Business Value (n = 76)*
17) 2023 *Optimizing Affiliate Engagement to Improve Performance of Key Regulatory Activities (open)*