Pursuing World Class Regulatory Information Management (RIM); Strategy, Measures and Priorities

Annual RIM Whitepaper
2016 Summer Edition
Based on our 2016 World Class RIM Study (n = 54)

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GENS & ASSOCIATES

Introduction

Our annual white paper is written to provide a clear industry status of Regulatory Information Management (RIM) highlighting the current state, key trends and priorities, investment focus, projected capability and organization change, and a comprehensive update on the provider landscape. This year we have an exciting addition that focuses on defining and measuring World Class RIM.

This world class journey started in 2014 where a top rated company from our 2014 RIM survey was disappointed in their peer ranking as they rightfully believed there was a tremendous amount of work to be completed and value to be realized. We reflected on this and quickly determined that having just a peer ranking without a target or "gold standard" to achieve would never give a true industry status. We went to work with the help of 18 companies in four design sessions in the fall of 2015 to define the first world class RIM baseline. This entailed detailed discussions and debate of "what is world class RIM?" and more importantly "how do you measure it?".

The theme from this research is plain and simple: we are in a period of unprecedented regulatory transformation and this will continue until at least 2020. Salient points from this year's research include:

1) 86% of companies are transforming some part of their RIM program
2) Companies with a Common RIM Model are 3.5 times more likely to realize business benefits, 18% more efficient and have 2.5 times more confidence in data quality levels
3) 85% of companies are projecting to realize key business benefits within the next 2 – 3 year
4) Emerging technologies are beginning to be used to create an end to end regulatory view
5) We will see a significant software provider market shift in the next three years

The information and graphs in this paper are primarily based on the results of our 2016 World Class RIM Study (54 companies), coupled with key learnings from participant debrief sessions, client work and our professional insights. This paper is structured as follows:

- Executive Summary
- What is World Class RIM?
- Comparing RIM Operating Models
- Applying Emerging Technologies in the RIM space
- Authoritative Source and Data Standards Update (IDMP/UDI/MDM)
- Regulatory Outsourcing Update: Trends and Supplier Status
- Vendor Landscape: Innovation Status, Market Share and Satisfaction Ratings

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

Executive Summary

Survey Demographics

A record 54 companies participated in this year's survey with a balanced representation of large, mid-tier, and smaller organizations (see Exhibit 1). We were pleased with the addition of several pure medical device and many smaller organizations giving us a better understanding of their RIM status, strategy, and investment direction. We analyze the data by size of company, geographic location (see Exhibit 2), and by product portfolio size and diversity to uncover unique trends and insight.

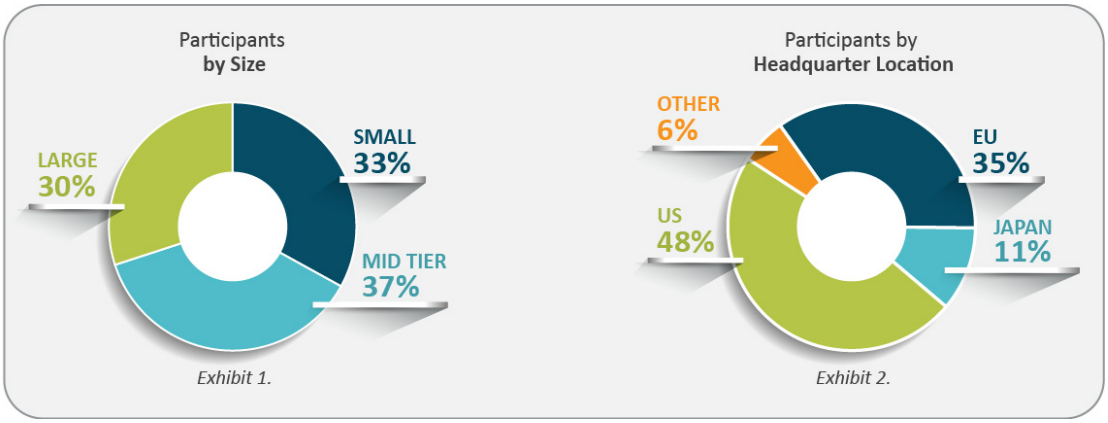

Exhibit 1. *Exhibit 2.*

Decade of Regulatory Transformation

We weren't surprised by the degree of transformational change underway as most of our clients have completed detailed RIM strategy and transformation planning work over the past several years with a common goal: substantially increase the efficiency and productivity of the global regulatory organization and key touchpoints while reducing compliance risk. The bottom line is improved "global" information management to substantially enhance the value, timeliness, and accuracy of the information for better internal decision making, health authority submissions and public/patient consumption.

Out of the 17 RIM capabilities (see appendix), 12 capabilities are undergoing transformational or incremental change in at least 70% of the companies surveyed. Exhibit 3 shows 8 RIM categories where at least 35% of respondents are undergoing transformational change including emerging data standards, global submission forecast accuracy, reporting and analytics, dossier management efficiency, product registration management, label management, supply release, and better manufacturing change control processes.

RIM Capability	% of Population		
	Transformation Change	Incremental Change	Total Overall Change
Data Standards (UDI/IDMP)	60%	28%	88%
Submission Forecasting	40%	47%	87%
Reporting and Analytics	36%	50%	86%
Dossier Management	42%	44%	85%
Product Registration Management	39%	45%	84%
Label Management	37%	41%	78%
Regulatory Archive	29%	46%	75%
Submission Document Management	34%	40%	75%
Health Authority Interactions (correspondence/Q&A	29%	44%	73%
Regulatory Requirements Intelligence	22%	49%	71%
Manufacturing Change Control	40%	30%	70%
Submission Production	22%	48%	70%
Health Authority Commitment	26%	40%	66%
Supply Release	35%	30%	65%

Exhibit 3.

The survey also explored the degree of organizational change and the status of business benefit realization from RIM investments. 52% of participants are in the process of implementing data governance roles and responsibilities and 44% are implementing the concepts of end to end process ownership.

We were surprised at the low degree of business benefit achieved today with only 8 participating companies having achieved a significant number of these benefits. 85% are expecting to achieve a significant level of business benefit realization over the next 2 – 3 years. These basic benefits such as reduced time to health authority submission, process integration efficiency, organizational productivity, reduced cost, and improved inspection/audit outcomes will greatly enhance the global organization.

When we combine the degree of ongoing transformational and incremental change, low business benefit realization, low efficiency rates for most RIM capabilities, and projected software solution change, it is clear the majority of industry is making major RIM investments. We believe industry is in the early stages of regulatory transformation with the peak projected in the 2018 – 2020 timeframe.

Industry RIM Status

For each of our major benchmarks, we provide a peer analysis so participants can gauge their standing relative to their peers. This is the first time we were able to provide a clear picture of regulatory information management in the industry. The results were not surprising given the degree of current and projected RIM capability investments and the transformational activities that industry is experiencing. Exhibit 4 provides the calculated world class RIM results of the participating companies sorted by company size. While we did not expect any organization to pass the World Class Level based on the transformation status, we did expect to have a handful of organizations in the strong performance band.

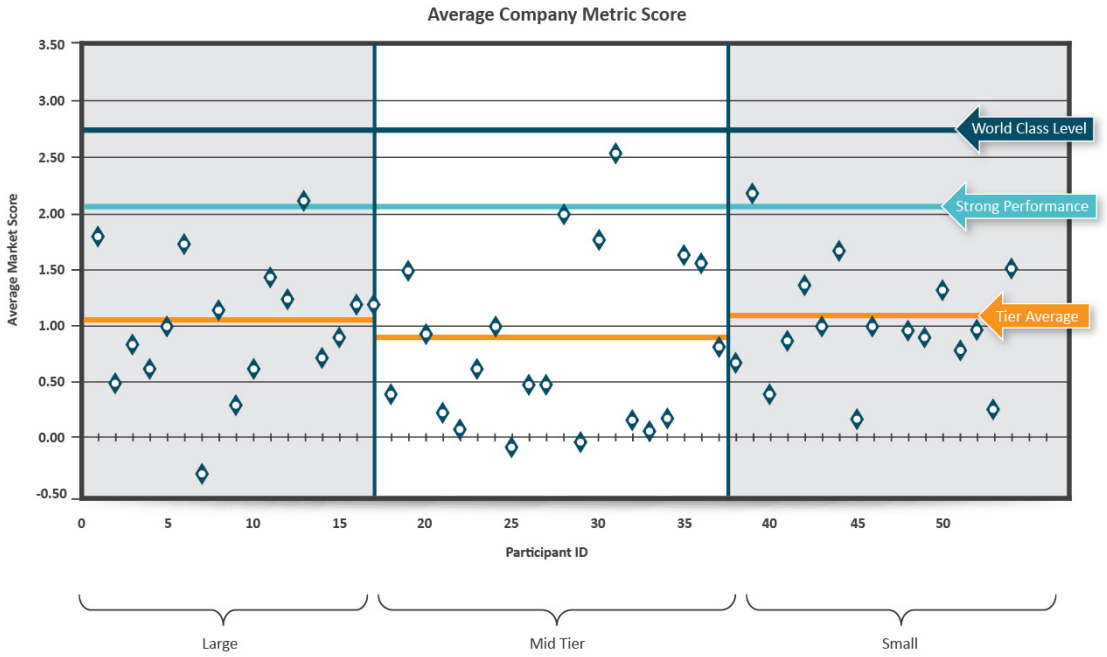

Exhibit 4.

Given the degree of "projected" investment, process and solution change, data quality enhancement, and organizational role change, we believe another 20% of the participants will move into the strong performance band and we expect 2 or 3 companies to surpass the target world class level by our next survey (scheduled for the fall of 2017).

Medical Device Status

Once the survey closed, we analyzed the data by size of company and, for the first time, by product type. The medical device sector, from an electronic submission of regulatory information standpoint, is about 10 years behind the medicinal product sector primarily due to the submission complexity and lack of electronic submission standards for medical devices among the world health authorities. The medicinal product sector completed significant submission harmonization work with the agencies 10 – 15 years ago that resulted in significant investments in document management, publishing, third party collaboration technologies, and authoring workflow. This drove the need to improve operational efficiency and reduce the time and cost of submissions that were growing in size, volume, and complexity.

The medical device sector is just starting on this digital journey. They tend to have a more autonomous business model at the regional and local affiliate level with a highly distributed regulatory operation. Pricing pressures and regulatory complexity at the regional level are causing many medical device organizations to rethink this decentralized model of regulatory information management and invest in standards and technology. We were not surprised that device participants scored in the lower region of

the world class plot (see Exhibit 5). The good news is there are many common practices to leverage from the medicinal product side. The solution providers are investing in areas where there are small but meaningful differences such as the registration management process, product release, and data standards (UDI compared to IDMP) between device and medicinal product divisions.

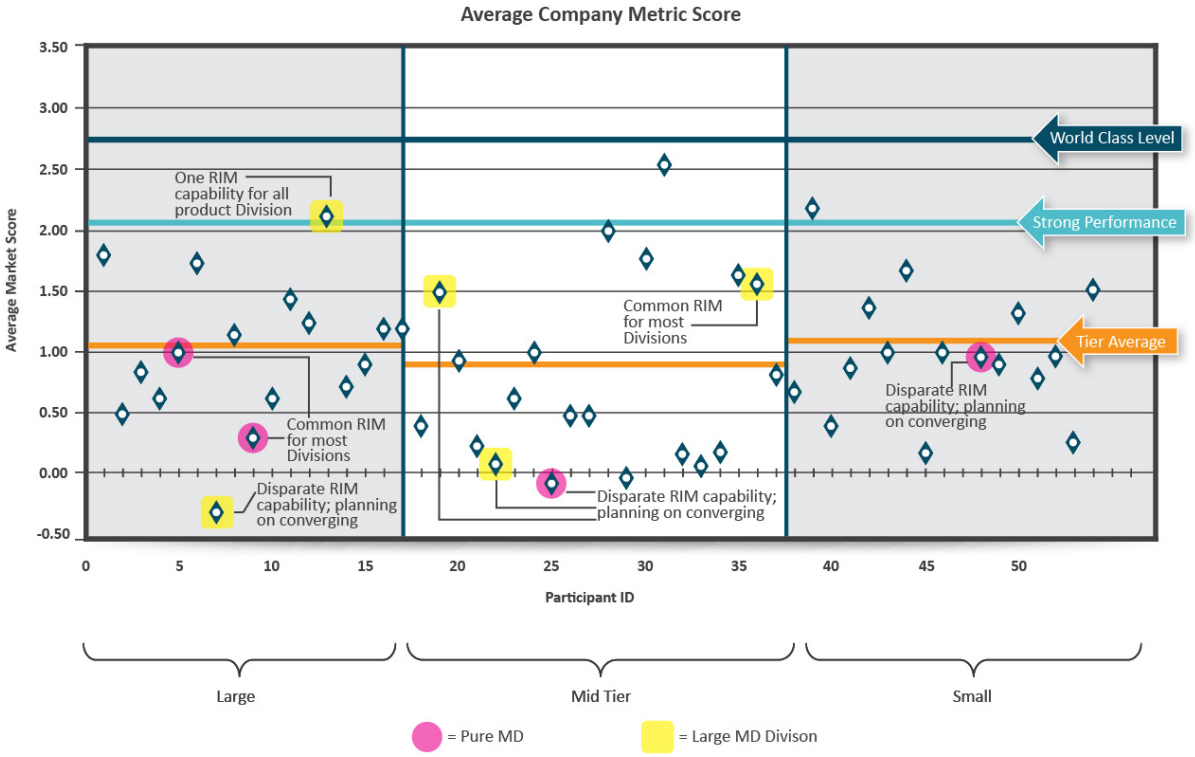

Exhibit 5.

VENDOR LANDSCAPE SUMMARY – SHAKEUP IN PROCESS

While we have a detailed section of this paper dedicated to the provider space, several results are worthy to be highlighted here.

The **degree of projected provider change** has increased substantially from 2014 which is significant as most RIM investments are typically 7 to 10-year investments. We believe the degree of change is driven by the combination of transformational change, shifting provider market leadership, and several notable providers that are on the decline coupled with the emergence of several new providers. The percent of survey participants that will change the following RIM capabilities within the next two years are:

- Heath Authority Correspondence /Q&A Management (72%) – No market leader
- Submission Planning and Forecasting (63%) – No market leader
- Registration Management (49%) – Market leadership
- Submission Document Management (39%) – Changing market leadership
- eCTD Publishing (36%) – Do to one primary provider exiting this space
- Label Management (34%) – No market leader

The **average provider satisfaction** rate had declined over the past four years and finally has stabilized (see Exhibit 6). We measure satisfaction on a 5-point scale where 3 is average or neutral. We believe the increase in satisfaction this year is due in part to many provider investments in usability and several new providers making headway into this space. These providers have much higher satisfaction ratings of their solutions and services.

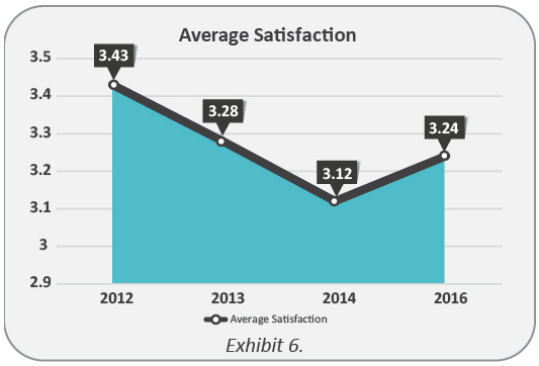

Exhibit 6.

The only exception to the trend of improving satisfaction is the large multinationals that have an average provider rating of 3.0, i.e. "neutral", compared to the overall average of 3.2. Mid-tier and smaller organizations rated their providers substantially higher.

Finally, we have our **proprietary innovation rating of 25 RIM providers** and are happy to report that several more providers are seen as innovating. On the other hand, 5 companies are clearly on a significant decline and are expected to be much less relevant in the coming years. We intentionally do not publish this data publicly as it is based on participant's "perceptions". However, we use it extensively in our client work and provider briefings.

What is World Class RIM?

Our Process

During the summer of 2015, we created a viewpoint of world class RIM and drafted the 2016 Survey in preparation for a series of design sessions with industry. We took great care to bring diversity into these sessions so different facets of industry were represented. We invited large multi-nationals, mid-tier and smaller organizations from each major region of the globe. We also wanted a good mix of product types inclusive of bio-pharmaceuticals, medical device, generics, and consumer. Many of these companies sent business and information technology (IT) representatives for the "grand debate". Our travels took us to Chicago, London (hosted by Product Life Group), New Jersey and one virtual session that brought many of the western United States companies together.

The debate and feedback was invaluable and we further tested several assumptions with other industry thought leaders. This resulted in our ability to create a survey that provides a precise measurement of a company's status relative to this new world class target and will allow our algorithm to be utilized as a diagnostic tool. This allows companies to "retake" a subset of the survey in coming years to understand their progress or, for newly participating companies, to get an accurate measure of their current state relative to this new standard.

World Class RIM – Five Elements, Eight Questions

We created an overarching model (see Exhibit 7) to drive the thinking and approach to the following eight questions in the 2016 survey (49 questions in all) as a means of measuring current state.

Exhibit 7.

1) **Efficiency Rating** – Utilizing a four-point scale (very efficient, efficient, not efficient, very inefficient), participants rated their efficiency status for the 17 RIM capabilities (see appendix) The rationale for the scale is to ensure companies make a clear choice; are you leaning towards efficiency or inefficiency!

2) **Business Benefit Status** – We had 12 categories of benefit realization with the rating scale being: 1) achieved benefit, 2) target by 2 years, and 3) not a priority.

3) **Metric Measurement Confidence** – It is one thing to create a measure, but another to have confidence in the data you collect. Those embarking on a metrics program realize this is a learning process and it may take several iterations to get it right so the data can be reliable for continuous improvement. Our scale for 13 benefit categories was 1) Yes, with confidence, 2) Yes, with low confidence, 3) No, planning within 12 months, and 4) No, not planned.

4) **Metric Milestone Status** – We asked: "Do you measure the time and have an approved standard milestone?" for 8 common regulatory activities (e.g. Core Dossier to local HA submission, HA question to response submission, label change approval to release to market). The scale was 1) Yes, measure with standard milestone, 2) Yes, measure with no standard milestone, 3) Standard milestone, but no formal measure, 4) Future priority, or 5) Not applicable.

5) **Operating Cost Understanding** – Leaders and Managers understand their budgets and often portions of their compensation are tied to this fiduciary responsibility. Historically, most organizations are excellent in budget management, however in our opinion, have too little understanding of the long term total cost of ownership that is driven by the annual run rate and operating cost. This point applies mainly to the central groups. The economic understanding at the regional and local affiliate level is often unknown or greatly underestimated. In our view for world class RIM, it is necessary to understand the RIM run rate and 5-year total cost of ownership. Participants were asked to indicate their level of understanding of their current RIM run rate at both the central and local affiliate level.

6) **Time to Provide Accurate Reporting to Common Regulatory Questions** – This is a very telling question and the survey results supported our underlying research hypothesis: "There a clear correlation between the time to report critical regulatory information and data quality confidence level and process/system efficiency". We asked participants how long it takes to report regulatory

information in six categories using the following scale: 1) hours, 2) days, 3) 1 – 2 weeks, or 4) greater than 2 weeks.

7) **Status of Global System Deployment to Affiliates** – World Class means the "world" can access and utilize the core RIM capabilities with minimal use (it never goes away) of spreadsheets and SharePoint at the local affiliate, regional level, and headquarters (global teams). While it would be rare for a true 100% global deployment, we accounted for the agent/distributor network by requiring the RIM capability be deployed to greater than 75% of the affiliate offices. We asked participants to indicate their status of 10 common RIM capabilities using the following scale: 1) In affiliate, 2) Planning on extending to the affiliate within 2 years, 3) No plans to extend or 4) No authoritative source currently.

8) **Authoritative Source Data Quality Levels** - It's one thing to have an authoritative source for regulatory information, but what is the confidence level of the data quality? A company might in fact have good data quality, but if there is a perception of poor data quality, you have a "confidence" challenge. We asked participants to rate the status of 10 authoritative sources by the degree of confidence (high, medium, low) with other options being a) create an authoritative source within 2 years or b) does not apply to our situation.

Comparing RIM Operation Models

For years, RIM software vendors have talked about the importance of having a common platform or suite of products for successful management of regulatory information. For industry, a "common" capability requires much more than a set of tools. It requires common processes across sites and geographies, standardized data definitions and entry criteria for the information captured within the RIM systems, as well as enforcement of those standards.

A key question in this survey was whether respondents had a common RIM capability for their products or not. Of the 54 companies that responded to the survey, 56% had a common capability for all or most of their products, and 44% had disparate (or separate) capabilities for their products. However, 80% of those with disparate capabilities were in the planning stage to converge their RIM capabilities. In terms of RIM programs, the industry has been in a state of transition for a few years and it appears this phase will continue for several more.

Those companies that have achieved a common RIM capability have spent significant effort aligning their business to support their RIM program. They have focused on establishing a global organizational structure, creating a governance structure with clear definition of roles and responsibilities, documenting end-2-end process ownership, and creating formal data standards with milestones related to the timely entry of regulatory information.

These efforts have resulted in a significant realization of business benefits and value compared to their counterparts with disparate RIM capabilities. In 9 of the 12 identified program benefit categories, those with a common capability were at least 3 times more likely to have realized the benefit, and at least 2 times more likely in the remaining 3 categories (range 2-9; see Exhibit 8). The largest gains are related to increases in user productivity, reductions in time to submission, reductions in operating costs and better business process integration.

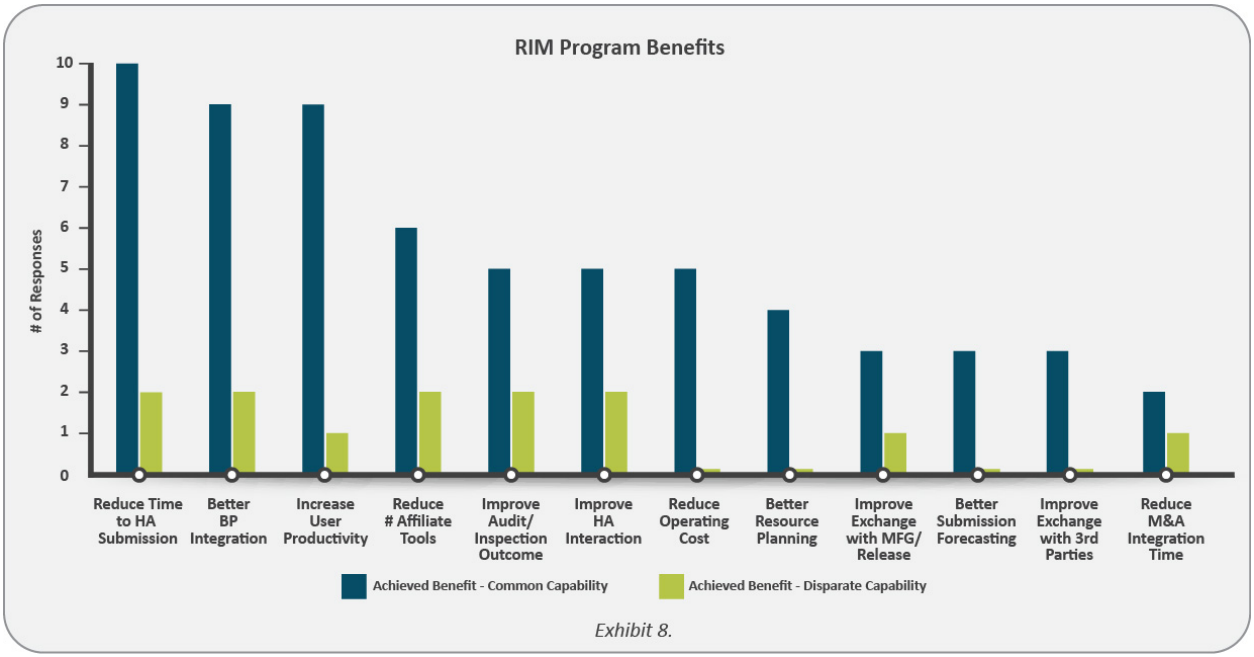

Exhibit 8.

In addition to realizing business benefits, those with a common capability were on average, 18% more efficient than their disparate capability counterparts. The largest efficiency gains between models were seen in Management of Product Registration Data (31%), Submission Document Management (25%), Dossier Management (23%), Submission Production (20% more efficient), Management of Health Authority Commitments (18%), and Management of the Regulatory Archive (17%). Disparate capability companies tended to have a higher efficiency in areas related to interactions with other departments such as, Legal Touch Point (15%), Manufacturing Change Control Touch Point (13%), and Supply Chain Touch Point (10%).

One of the most important aspects of any RIM program is to ensure that the time and effort expended in capturing the information results in accurate information being available quickly to assist in decision making. There is little value in capturing information just for the sake of capturing it. Users of the information must have confidence in what is provided by the systems without the need to "check" its accuracy with other parts of the organization. Worse yet is maintaining an alternate source of data, such as a spreadsheet. Once again, companies with a common capability performed equal to or better in all categories than their disparate capability counterparts. Common capability companies were six times more likely to have confidence in their data related to 2 key regulatory compliance areas -

Meeting Health Authority Compliance Reporting and Open Health Authority Commitments (see Exhibit 9).

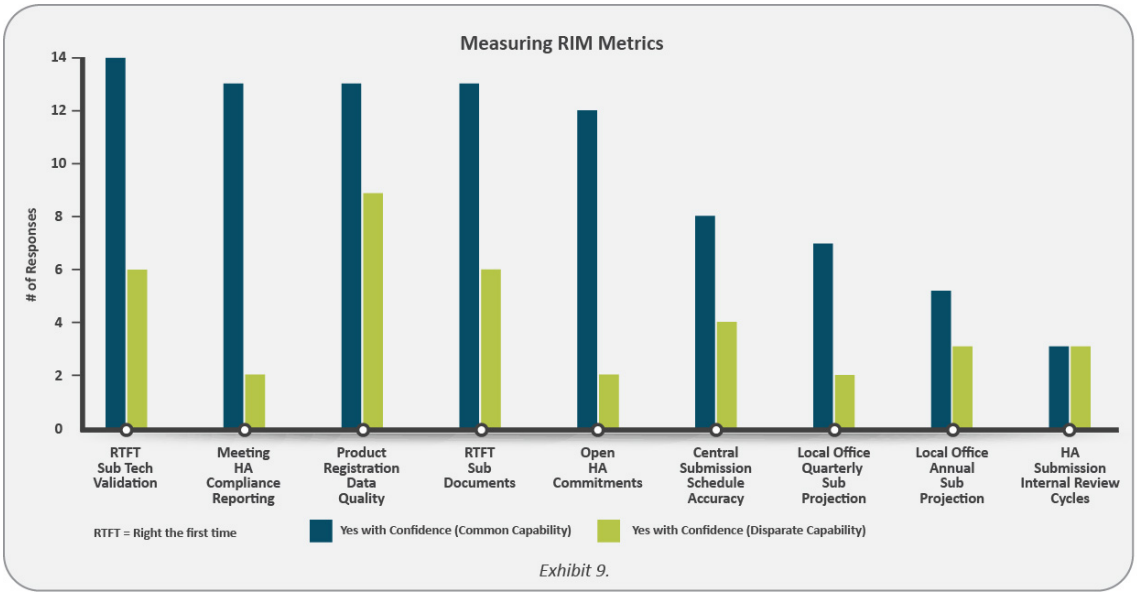

Exhibit 9.

In addition to having confidence in the data, the organization must be able to access the data quickly for business purposes such as determining the impact of potential product recall or at the request of an inspector to aid in business decision making. This critical data is twice as likely to be available in a matter of hours to a company that employs a common RIM capability (see Exhibit 10).

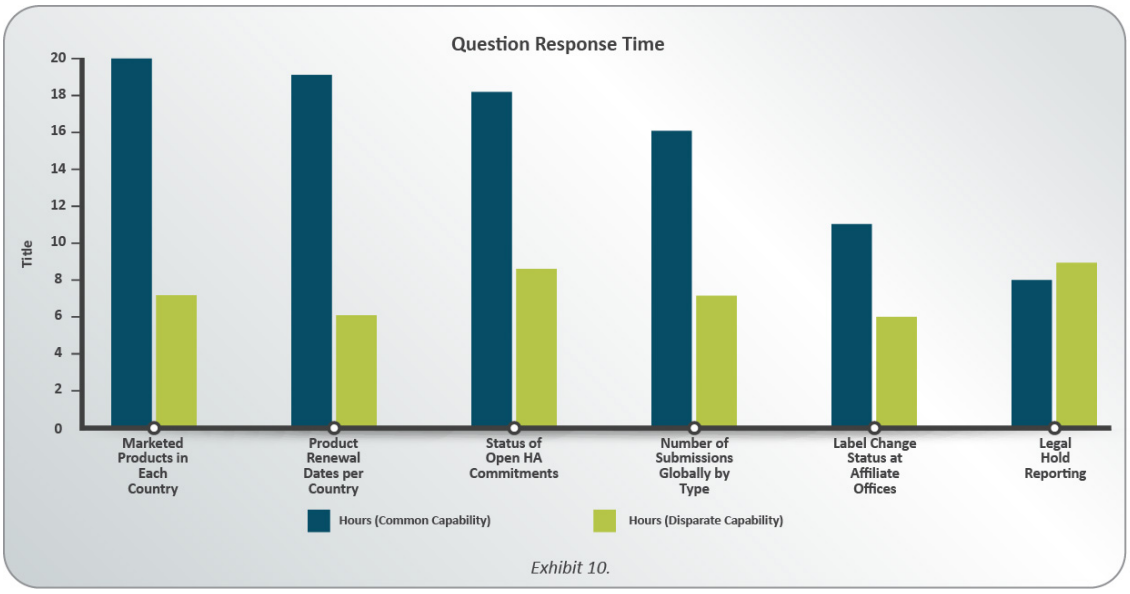

Exhibit 10.

Industry believes that a common capability is a benefit to their business and this survey confirms this belief.

Applying Emerging Technologies in the RIM Space

We have been discussing and anticipating the promise of emerging technology to significantly improve Regulatory Information Management (RIM) systems for the last few years. Historically traditional methods, such as more powerful servers and faster internal networks, shared workspaces and incremental software upgrades have provided relatively little business improvement.

With the advent of significant new regulatory requirements, such as IDMP, and the continuing recognition that regulatory information is a largely underutilized corporate asset, we see four promising emerging technology areas as relevant to world class management of regulatory information.

1. Master Data Management (MDM)

It is widely recognized that establishing and using data and document standards across regulatory systems and within systems that contribute to regulatory systems helps ensure regulatory information is more useful and accessible.

In the past, there have been major obstacles to establishing formal regulatory master data management programs. Regulatory groups believed that their systems, process and data met their minimum needs and typically were frustrated by the existence of so many "niche" systems and the cost of integrating these systems. As long as regulatory requirements were met and the company was compliant, even if it sacrificed cost and efficiency, it was "acceptable". IDMP and UDI are changing the thinking with between 50% – 66% looking to adopt a MDM approach.

Our 2016 survey demonstrates that efficiency of various key regulatory capabilities is very low across the industry (see Exhibit 11), only one regulatory capability (submission production) has a "ok" efficiency rating with the overall study average at only 39%.

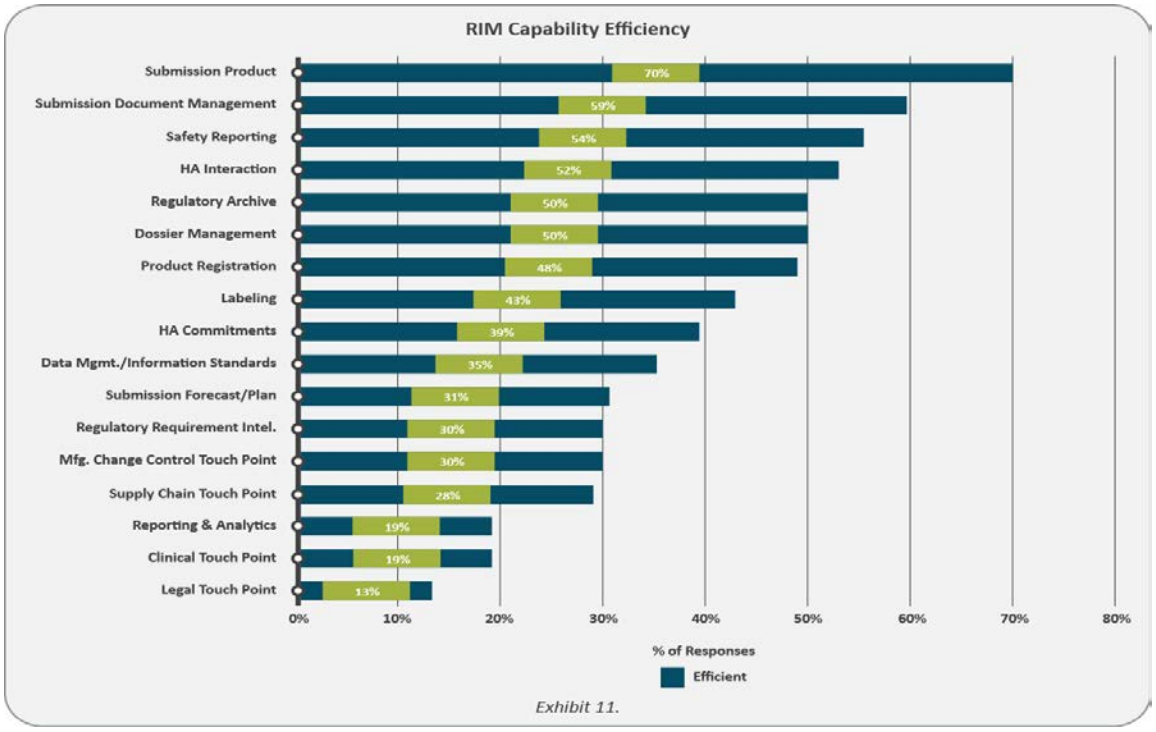

Exhibit 11.

We now see an increase in the recognition that *efficiency* as well as effectiveness is important as new internal and external requirements are identified. A key external requirement is to submit IDMP data for marketed and investigational products, and structured substance information over the next few years. IDMP data source and data quality analyses have shown that meeting IDMP submission requirements will be a multi-year, multimillion dollar effort for mid-size and large biopharmaceutical companies in part due to the need to assemble data from multiple sources within regulatory and non-regulatory areas, such as safety, clinical and manufacturing.

More efficient regulatory information management built on improved data standards, standard processes and true authoritative source identification is emerging as a critical need spurring the re-evaluation of enterprise MDM programs and governance. We also believe that a master data management approach is more cost effective over a 5 – 7-year total cost of ownership period.

2. **Business Process Management (BPM)**
Some companies are investing in BPM solutions to support standardized business process execution and to simplify the use of complex regulatory software systems. In the last few years, we identified the need to simplify the use of technology for infrequent users of systems. A common complaint is the need to understand a fairly complex user interface and drill down several screens to enter one simple regulatory transaction e.g. a country gains product approval from the local health authority and wants to update the product registration system where the registration status is contained and scan in the approval letter to the submission content management system. This becomes a time consuming transaction in two large and complex systems. This is why some affiliates struggle with compliance and timely data entry.

BPM systems that can fully understand each business process step and context, and provide an easy way to access the specific field in the underlying RIM system could provide significant improvement in timeliness and quality of data in RIM systems.

3. **Software as a Service (SaaS) / Cloud Computing**
We have been tracking the interest and adoption of SaaS for regulatory capabilities since 2011. Our data show that while there is significant interest in adopting a SaaS solution for many of the common RIM capabilities, there has been relatively little actual SaaS implementation. The low adoption rate, especially compared to other industries and to some non-regulatory functions in pharma, is likely due to a complex mix of factors including, but not limited to:

- Concerns about data security
- Uncertain ability to meet regulatory inspection criteria
- Lack of evidence of success of peer regulatory groups
- Concern the current system, data and business process environment is not sufficiently mature to be moved to a SaaS environment

However, lessons from other industries and other functional areas in life sciences show that solutions can be implemented faster, made globally accessible and can often be operated at less overall cost than internally provisioned solutions.

In addition, the data and process standardization that is typically part of global SaaS deployments is

likely to lead to significantly better global access to the authoritative source of regulatory data.

Our 2016 survey data (Exhibit 12) shows a significant increase in electronic Trial Master File SaaS implementations since 2014. We are tracking this closely to see if it will carry over to the highly integrated RIM capabilities.

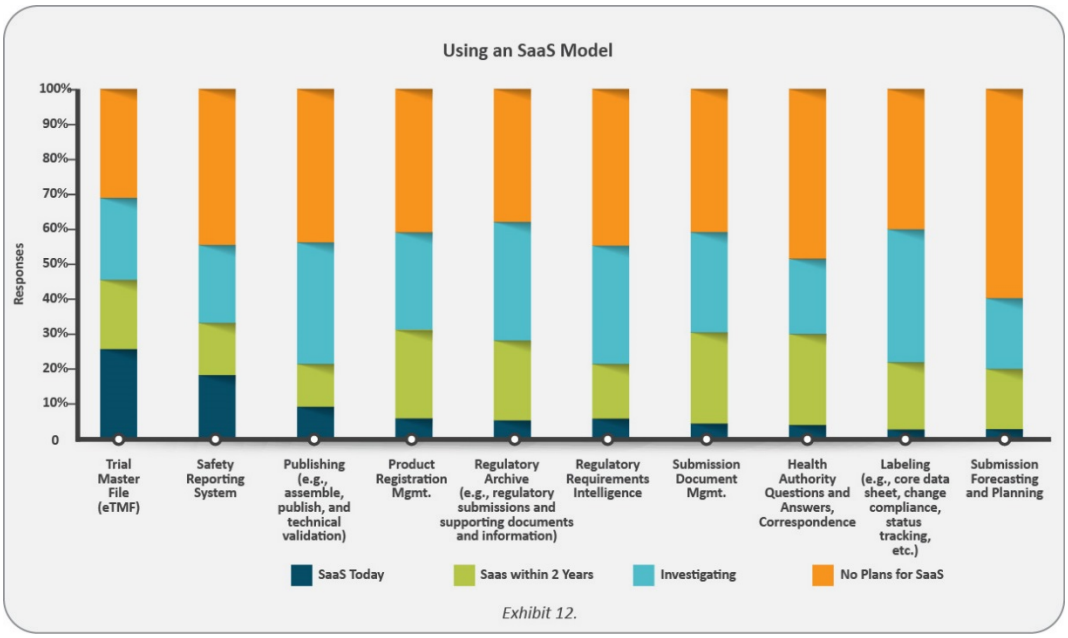

Exhibit 12.

Artificial Intelligence

Several IDMP data source and data quality analyses conclude that at least 50% of the data needed to meet the current IDMP reporting requirement is located in unstructured documents and reports. Some of this data is unique to the source and some is potentially duplicative or conflicts with other sources. A key emerging requirement is to efficiently and effectively locate the specific data in unstructured sources. The data must then be extracted or, as a minimum, highlighted for evaluation.

Software solutions from other industries, such as the intelligence and legal e-discovery communities, are being investigated to determine if unstructured sources can be mined for IDMP data. These solutions use advanced mathematical methods to identify contextual meaning and relationships of text in unstructured documents without the requirement of coded keywords or pre-established dictionaries.

While these tools are in the early evaluation and proof of concept stage, further analysis and development could provide a very useful service in analysis of unstructured data sources for IDMP and more broadly in regulatory information management search and reporting.

We believe there will be a continuing development and adoption of new technology over the coming years, especially in the search for more efficient regulatory information management methods and practices.

Authoritative Source Data Standards Update

Designation of specific RIM systems and repositories as the authoritative source for regulatory information has been the standard for many years as evidenced by our previous RIM research. In 2016 we took the next step towards understanding regulatory information authoritative sources by asking each company to assess their confidence in the data within the authoritative source for 10 essential capabilities. Exhibit 13 shows the percent of companies expressing "High Confidence" in the data for each of these capability.

Exhibit 13.

Fewer than 50% of the companies expressed high confidence in any authoritative source except Safety Reporting. The overall average number for "High Confidence" is only 34%, however there is a significant increase in average confidence across all RIM capabilities among companies with a "common" RIM capability. Companies with a "disparate" RIM capability only report an average high confidence level of 20% compared to 50% for a "common" RIM capability.

Those participants with a relatively low data confidence level in their authoritative sources correlates with the relative low efficiency, achieved benefits and limited ability to report / query common regulatory information in a timely manner.

Limited confidence in authoritative sources also contributes to the anticipated level of effort needed to compile data for required IDMP submissions. As shown in Exhibit 14, data ownership, governance and organizational changes are key elements to IDMP programs. We believe these activities reflect both the fact that IDMP data is found in multiple organization or functions and that authoritative sources for IDMP data have not be agree upon nor verified to the extent needed to produce a validated submission.

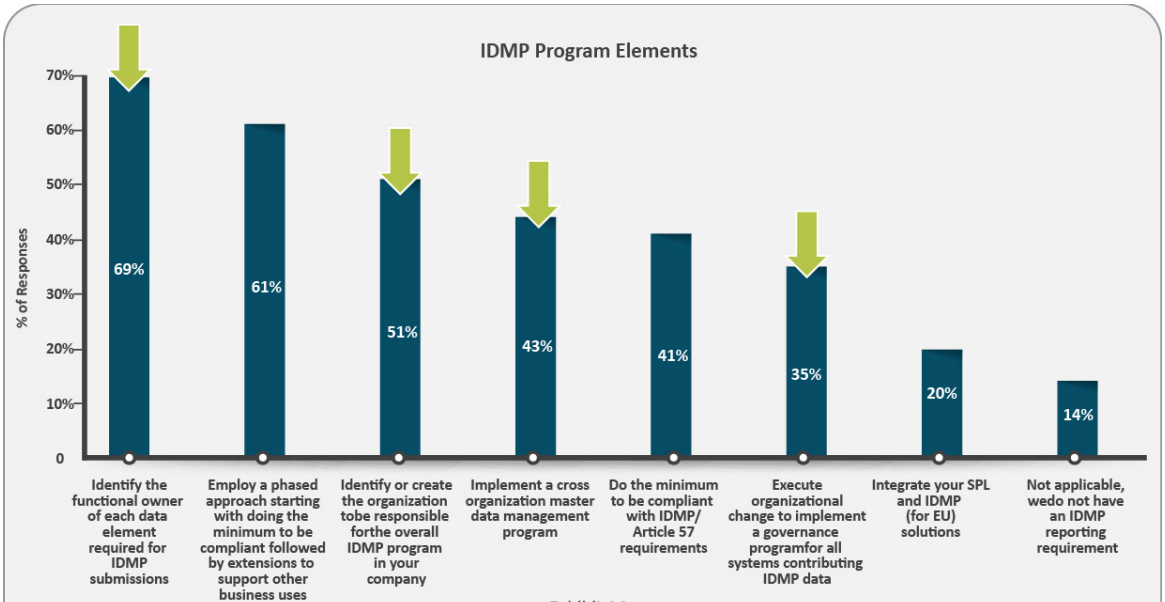

Exhibit 14.

Although our research indicates there is significant work to be done to improve RIM, we believe the large degree of change that is in progress across the industry will result in more efficient management of regulatory data and an improvement in the quality of regulatory information.

We also modeled the anticipated total industry spend for IDMP compliance several times and will conduct a final analysis once the specification is finalized. Our latest thinking is a total spend of $410 million dollars for the top 250 with 55% being business related (data remediation, manual process development, initial data load), 26% being project analysis (detailed gap analysis and program oversight), and the remaining 19% being technology spend (information staging area and the actual submission technology).

Regulatory Outsourcing Update

We have tracked dossier outsourcing since the inception of our industry benchmarks in 2007. Since 2014 outsourcing has been considered a common practice with many qualified suppliers having positive satisfaction ratings. There are a variety of viable outsourcing models ranging from individual application types to full function outsourcing.

In the early years of outsourcing, most companies had cost reduction as a primary driver with the ability to leverage publishing resources in low cost regions (e.g. China and India). While this remains an important factor, companies have organizational flexibility (managing submissions peaks) and increasing operational efficiency, as primary drivers with talent management (ensuring the right people are available for the right job) as an increasing important business driver (see Exhibit 15).

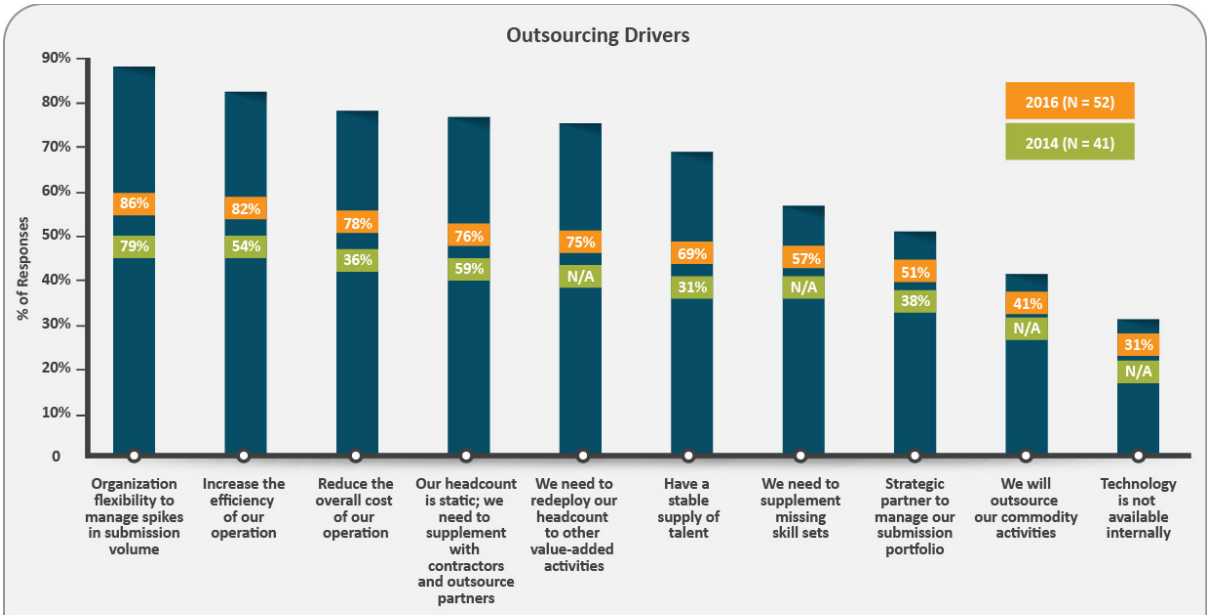

Exhibit 15.

Outsourcing activity levels have remained about the same since 2014 when we declared "outsourcing is a common practice and no longer a growing trend". The most commonly outsourced activities are investigational or new marketing application submission publishing, small maintenance submissions, local affiliate submission publishing, safety case processing and safety reporting. The two biggest growth areas are IDMP submissions (projected) and product registration data maintenance (see Exhibit 16).

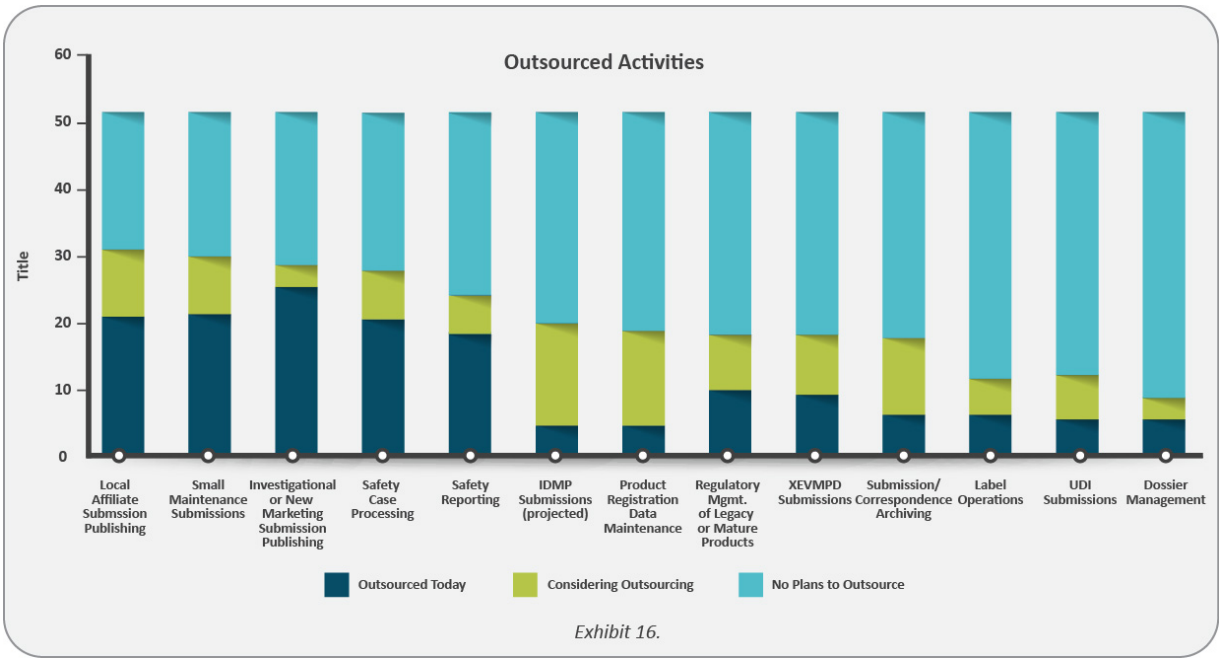

Exhibit 16.

Which activities are outsourced can vary by tier. Exhibit 17 details the most common outsourcing activities, least common outsourcing activities and highest growth activity by tier.

Company Tier	Most Common Activity Outsourced Today (more than 35% of companies)	Activity Most Likely to Outsource Today Compared to Other Tiers	Activity Least Likely to Outsource Today Compared to Other Tiers	Highest Growth Potential (more than 25% companies considering)
Large	■ Investigational or New Marketing Application Publishing ■ Small Maintenance Submissions ■ Safety Case Processing ■ Submission / Correspondence Archiving	■ Submission /Correspondence Archiving ■ Product Registration Data Maintenance ■ UDI Submissions ■ IDMP Submissions	■ Local Affiliate Submission Publishing ■ Safety Reporting	■ Small Maintenance Submissions ■ Safety Reporting
Mid	■ Investigational or New Marketing Application Publishing ■ Small Maintenance Submissions ■ Local Affiliate Submission Publishing ■ Safety Case Processing ■ Safety Reporting	■ Local Affiliate Submission Publishing ■ Safety Reporting ■ Management of Legacy or Mature Products	■ Dossier Management ■ IDMP Submissions ■ Product Registration Data Management ■ Submission / Correspondence Archiving	■ Submission / Correspondence Archiving ■ Product Registration Data Management
Small	■ Investigational or New Marketing Application Publishing ■ Small Maintenance Submissions ■ Local Affiliate Submission Publishing ■ Safety Case Processing ■ Safety Reporting	■ Local Affiliate Submission Publishing ■ Safety Reporting	■ IDMP Submissions ■ Product Registration Data Management ■ Label Operations ■ Submission / Correspondence Archiving	■ Management of Legacy or Mature Products ■ Product Registration Data Management

Exhibit 17: Outsourcing Activities by Tier

The outsource services provider landscape has remained consistent since our 2014 survey. Large and mid-tier companies tend to outsource to established providers while small companies tend to use a variety of smaller outsource companies. Our list of service providers that we track has grown to 15 due to the increasing market opportunity and "bundling" of services such as dossier management, product registration, and safety reporting. Parexel and Accenture have retained their market leadership position and continue to have positive customer satisfaction ratings. Other providers having overall positive ratings from multiple sponsors include Genpact/Pharmalink, TCS, and ProductLife Group.

We also utilize our benchmark data to conduct addressable market analysis (AMA) to provide data of the total market opportunity in our consultancy work. Our first AMA study was conducted in 2011 with updates in the summer of 2015 and 2016. We have eight service categories that we track of which four are related to different types of dossier outsourcing (new market/investigational applications, life cycle management, affiliate e-submissions, and report level publishing). In 2011, the total regulatory service market opportunity was ~$580 million, this increased to ~$840 million annually in 2015. The four categories of dossier outsourcing totaled ~$260 million in 2011 and has increased to $286 million in 2015. The major service outsourcing spend increase was due to regulatory affairs consulting, IDMP compliance, and overall RIM consulting (strategy, transformation execution etc.).

We also conducted a pulse survey focused on legacy product outsourcing in late 2015 which combines the regulatory operations (dossier management/production and product registration maintenance), regulatory affairs, and safety reporting activities. Several mid-tier companies are experimenting with this new model and if adoption increases, it is a "game changer" for the provider space. In our opinion, there are very few outsourcing providers that have a combined "mature" capability for full regulatory operations, global regulatory affairs and safety in our opinion. The regulatory services addressable market will substantially increase by an additional $200 - $420 million annually if legacy product outsourcing is adopted.

Vendor Landscape: Innovation, Market Share and Satisfaction Rating

Since we started our benchmarks in 2007, we have seen moderate changes to the provider field and the pace of change is picking up in several different service and solution areas. First, we witnessed several waves of provider mergers and acquisitions since 2009 and this will be accelerating, in our opinion, as we leave 2016 and go into 2017. Based on our market analysis data, the addressable market has expanded since our baseline analysis in 2011. We view the regulatory solutions and services as a $6.7 billion market (5 year) for the top 500. Exhibit 18 shows the split between services and solution spend. The services spend has dramatically increased over this period and the solution spend has had a moderate increase due to IDMP/UDI procurement and smaller organizations investing in formal RIM tools. We define services in eight categories (investigational and new market publishing, report level publishing, affiliate electronic submission, small maintenance submission – life cycle management, strategic writing, regulatory consulting – product and geography strategy, product registration data maintenance, and finally RIM consulting (strategy, IDMP/MDM analysis, data governance, and process consulting). RIM solution categories are submission document management, eCTD publishing, product registration and commitments, submission forecasting and planning, IDMP, and PC/Safety.

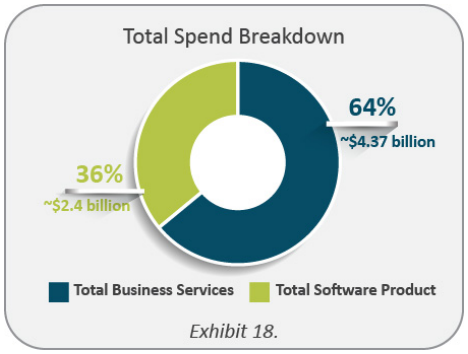

Exhibit 18.

WHERE IS THE SPEND?

Most companies have completed their IDMP analysis and are in the technology and services RFI/RFP stages for remediation on the medicinal side. Most of the medical device side has completed buying for UDI compliance. While there is major procurement activity on the IDMP side, we are witnessing a significant spend for many companies for modernization of submission content management platforms (39%), continued investment in labeling content management and compliance tracking (34%), product registration management (49%), HA correspondence management (72%), and submission forecasting and planning (63%). We believe some of this spend is due to a couple of providers that are in a major decline, especially in the submission content management, label content management, and eCTD publishing areas.

Content Management Modernization

We first became aware of accelerated content management spend during our early 2015 pulse survey of 21 companies entitled "Next Generation Content Management" where 68% were forecasting either major change or areas of major change (see Exhibit 19). It was clear from this data that between 2016 – 2019, the majority of large multi-nationals and mid-tier companies would be modernizing, not so much their individual systems (submissions, eTMF, manufacturing etc.), but consolidating on a platform and looking to simplify the entire environment if possible. During the 2002 – 2005 timeframe, many companies invested heavily in submission content management and these tend to be 10 year investments. This natural "spend cycle" coupled with a change in the provider space is accounting for this acceleration of spend.

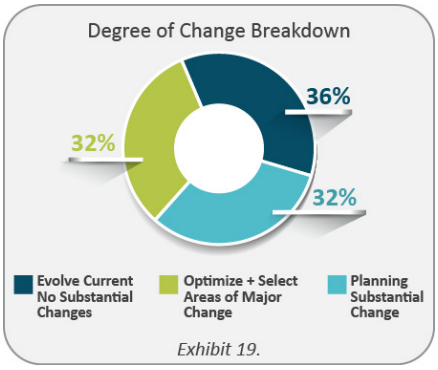

Exhibit 19.

Veeva has emerged as a viable solution for content management and is dominating the eTMF space for larger organizations and winning in the submission space for mid-tier and smaller organizations. EMC is investing heavily in their Life Science Solution set with the new D2 platform giving an alternative to other pure Documentum based solutions such as FirstDoc and Generis Cara. At the time of this whitepaper, the Dell/EMC merger was completed and immediate communication of the content management (Documentum) division being divested to Opentext. We will provide a viewpoint of this transaction in our October 2016 blog.

We also see new comers Amplexor and Acuta emerge in the smaller and mid-tier for both content management and the data management side (e.g. registration management). While these providers are on the upswing, we also see a phase-out of NextDocs and IBM Score solutions, moderate reduction in market share for CSC First Docs and customized Documentum, and finally no movement in those that have a SharePoint platform.

Part of the submission content management modernization is combining the submission source documents, published output, health authority correspondence / Q&A, and the regulatory archive. In the old paper archive days, documents were filed chronologically in a physical storage room (active and archive). An EMC announcement a couple of years ago combining these different document types has forced others to adopt this logical approach. This area will see significant solution change in the next two years (see green bars in Exhibit 20). Please note the following two graphs have the following data format:

1) Blue bars representing the number of participants with this solution set "today"
2) Green bars representing the expectation they will move "away" from this provider (we don't know where they will go)
3) Red diamond represents the "average satisfaction" score (5-point scale with 3 being average or neutral)

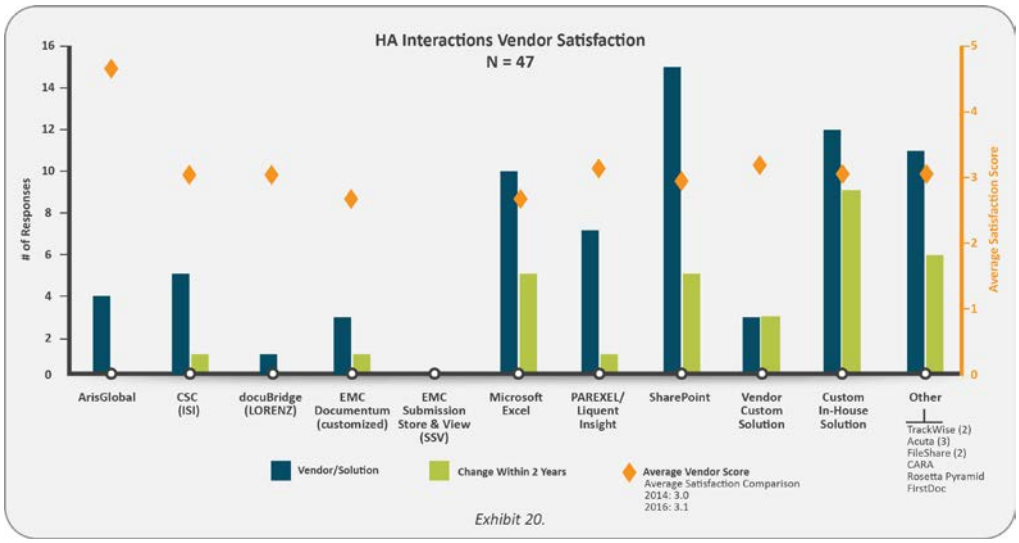

Exhibit 20.

PLANNING AND TRACKING – MATURE SOLUTIONS REQUIRED

Most companies have completed deploying their Product Registration capability and are focused on increasing data quality with organizational role (data stewards) and better metric work. PAREXEL continues to be the clear market leader with ArisGlobal a consistent second. We also see Acuta emerging for smaller organizations. We hope several new providers get some traction to make this a very competitive market.

Submission planning and label change compliance tracking solution are still in the maturing stage. The current market leader for submission forecasting and planning is Microsoft Excel while the label change compliance tracking has Intragras, PAREXEL and ArisGlobal as the primary providers with many participants having internal customized solutions (see Exhibit 21).

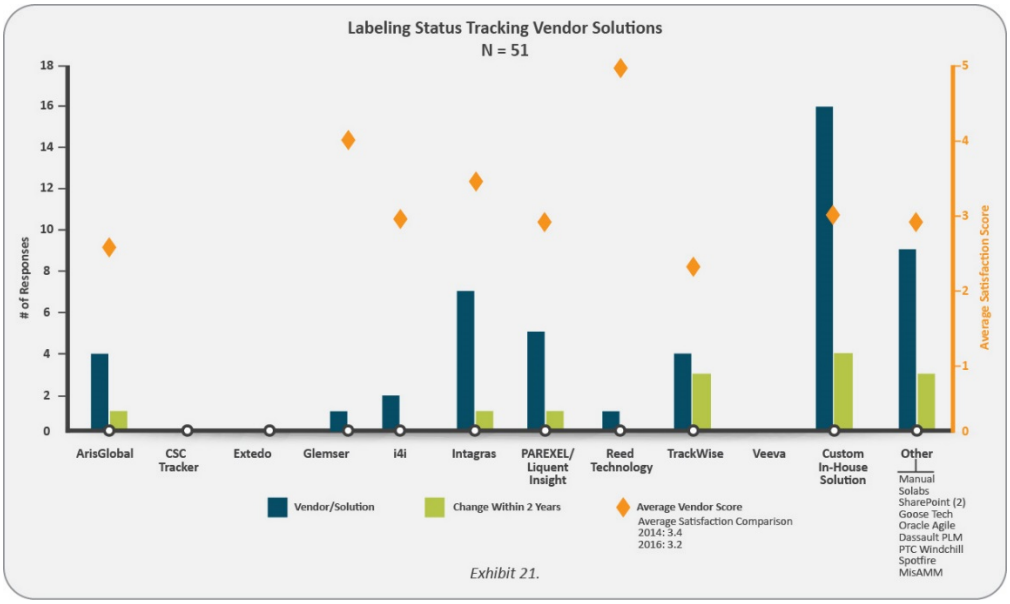

Exhibit 21.

In the coming years, we hope to see several of these players provide the ability to support all three (registration, submission planning and label change compliance tracking) well so there is a simplification in the solution set similar to what is going on in the content management space. There is certainly a large business opportunity for those providers who can accomplish this.

INNOVATION

Increased innovation has been a theme for providers for quite some time and progress is being made on usability for the infrequent user (local affiliate, regional office, regulatory affairs for global products). There is still plenty of opportunity to further realize end-2-end regulatory information management at your fingertips without going into 5 or 6 systems to get "pieces of information". Some of the innovation is coming from emerging technology such as business process software, master data management, analytics, and artificial intelligence.

We have been tracking "perceptions" of primary RIM providers (see appendix) for three years now. We dropped 3 providers from our 2014 list and added 9 new providers this year. Survey participants were asked to respond with their perceptions of each provider using the following scale. Is the provider: 1) pushing industry (or innovating), 2) keeping up with industry (a responsible and positive rating), or 3) on the decline? In 2014, 63% of the providers had a positive rating (innovating + keeping up with industry) and this has risen to 68% in 2016. In contrast, this year, 8 of the 25 providers received overall negative ratings. Finally, when we cut the data by size of company, there are some very different perceptions of innovation with the same provider based on company size.

In addition to the 25 primary RIM providers (see appendix), we are constantly looking at new potential players and evaluating their solutions and value to industry. Over the past 12 months, we have started assessing Acuta, Ennov, Cabeus, Cunesoft, and Content Analyst (bought by kCura).

PROVIDER LANDSCAPE CONCLUSION

There are many newcomers in the provider space and several historic RIM players on the decline. We are glad to see average satisfaction ratings improving (mainly due to the newcomers) while technology innovation is still a gap with some progress being made. The addressable market has increased due to smaller organizations investing in RIM and the significant spend for IDMP compliance. While there are still some areas that are underserved (submission forecasting and planning), there is a large opportunity for innovative providers that can address the "end to end" regulatory view coupled with advanced analytics, visualization, and reporting capabilities.

White Paper Authors

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Greg Brolund 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 Masters of Chemistry degree from the American University in Washington DC.

Sarah Powell 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's of Science degree in Nutrition Science from the University of California, Davis, is Regulatory Affairs Certified in the US and EU; and a RAPS Fellow.

Appendix

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*

17 RIM Categories

1. Data Management and Information Standards (IDMP, UDI)
2. Dossier Management (content plan, distribution, archive)
3. Health Authority Interactions (Q&A, Correspondence)
4. Health Authority Commitments
5. Labeling (core data sheet, status tracking, etc.)
6. Product Registration Management
7. Regulatory Archive
8. Regulatory Requirements Intelligence
9. Reporting and Analytic
10. Safety Reporting
11. Submission Forecasting/Planning
12. Submission Document Management
13. Submission Production (assemble and publish)
14. Touchpoint: Manufacturing Change Control
15. Touchpoint: Product Supply Release
16. Touchpoint: Clinical
17. Touchpoint: Legal

Providers in Innovation Rating (sorted alphabetically)

1. Accenture (includes former Octagon)
2. Appian
3. Amplexor (includes former Infotehna)
4. ArisGlobal
5. Arivis (includes former Mission 3)
6. CSC (includes former ISI / FCG)
7. EMC
8. Extedo
9. Generis
10. Genpact (includes former Pharmalink)
11. Glemser
12. I4i
13. Intagras
14. LORENZ
15. Microsoft
16. Microsystems
17. Oracle
18. Qumas
19. NextDocs
20. PAREXEL (includes former Liquent)
21. Planisware
22. Instem (includes former Samarind)
23. SAP
24. Sparta
25. Veeva