Next Generation Regulatory Information Management and Intelligence: Strategy, Investments, and Status

Annual RIM Whitepaper
2015 Winter Edition
Based on our fall 2014 Empirical Industry Study

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GENS & ASSOCIATES

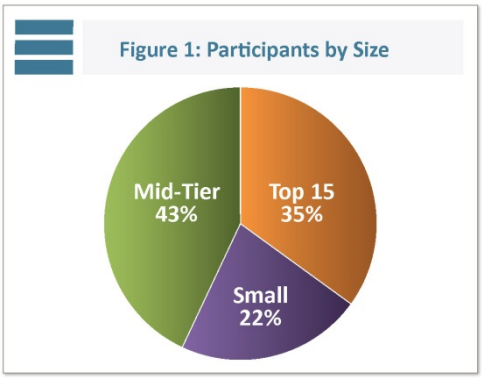
Introduction

Our annual white paper is written to provide an industry status of Regulatory Information Management (RIM) containing the current state, key trends, investment focus, projected change, vendor landscape and a perspective of what is 2nd generation RIM. This is based upon several recent large biopharmaceutical benchmark studies, client work, and our insight. RIM continues to increase in importance and evolve with most companies focusing on updating a significant portion of their RIM capabilities. We see the following salient points as key 2015 themes:

1) RIM is being viewed more strategically from a functional and geographical standpoint and gaining "C" suite attention
2) There is a significant push to have most local affiliates participate in the global RIM program
3) RIM drivers and business cases have evolved from "primarily compliance" to an equal emphasis on realizing efficiency and productivity benefits
4) Many have or are planning organization structural change to support RIM goals
5) Dossier outsourcing has shifted from a growing trend to common practice
6) Declining vendor satisfaction levels driven by usability issues and innovation gaps are challenging the current vendors and providing an opportunity for new players

Most data graphs are from our fall 2014 RIM study of 41 companies having a solid distribution of company size (see Figure 1) and geographic location (EU, Japan, US). The whitepaper structure is:

- Executive Summary
- RIM Investment Priorities and Trends
- RIM Capability Update
- 2nd Generation RIM Model Perspective
- Regulatory Intelligence Capability Baseline
- RIM in the Cloud status
- Information Architecture / Data Standards Adoption (IDMP)
- Regulatory Outsourcing: Status, Trends, and Supplier Summary
- Vendor Landscape: Innovation Status, Market Share and Satisfaction Ratings



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

Special thanks to Adam Sherlock and Erick Gaussens of Product Life Group who hosted a survey design session in Frankfort Germany and supported European participant enrollment.

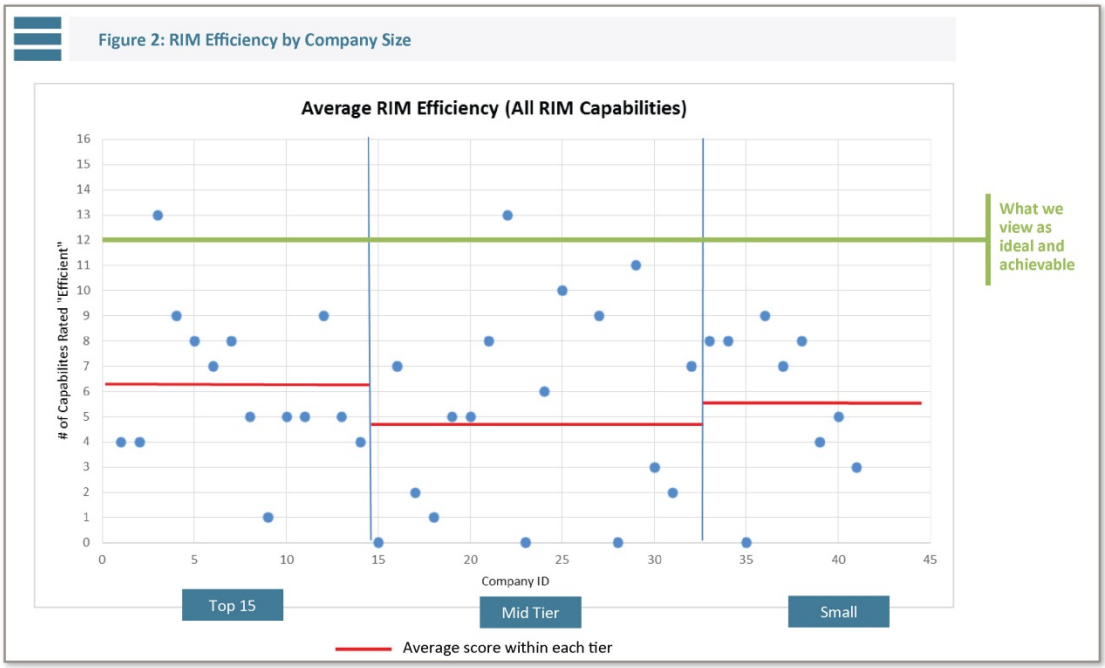
Executive Summary

We left off in 2013 with the exploration of a simple question from our spring 2013 RIM study (n = 37 companies): was RIM being positioned and managed as a corporate asset? This turned out to be true for many companies and emerging for the remaining.

Our fall RIM 2014 research reports the strategic value is increasing with the expectation of improved efficiency within regulatory and three critical touch points: 1) local affiliate office, 2) the manufacturing change control process, and 3) supply release process. While effective compliance is essential, executives expect improved efficiency, better productivity, and the repurposing of headcount to higher skilled activities from their RIM investments.

For the 41 study companies, we focused on the efficiency opportunity and where it specifically lies as there is significant room for industry improvement. We plotted the participants by market tier (see figure 2) and averaged their "efficient" and "not efficient" scores in 16 RIM categories (see appendix) for peer comparison. We have a pragmatic view that a highly efficient RIM environment, given all the functional, geographic, conflicting regulatory standards and lagging technology is not 100% achievable today; however we strongly believe that 75% of RIM categories can indeed be efficient and is achievable for most organizations (green line). The investment priority section further breaks this down.

Figure 2: RIM Efficiency by Company Size



Another area of targeted exploration was the status of cross divisional RIM, meaning those companies that have many product type divisions such as pharmaceuticals, biologics, medical devices, vaccines,

consumer, generics, diagnostics, and animal health to name a few. Over half had cross divisional RIM programs and this increased dramatically to 77% for the larger multi-national companies. We decided to conduct a pulse survey of 8 companies in the top 15 (by revenue) to further understand where their program is and investigate if structural change and system convergence were key characteristics? Figure 3 shows that many have already deployed cross-divisional RIM while several others are taking initial steps to converge their organization and RIM capabilities. Figure 4 shows the breakdown of RIM components and what has been consolidated to date, planned to be consolidated, and planned to be left independent. Product Registration, Submission Planning, and Publishing were deemed to have the most value for the initial convergence steps followed by content related capabilities such as Submission Content Management, Health Authority Correspondence Management, and Labeling. One area where half did not see the convergence value was Ad/Promo capability where organizational structure has a large bearing on whether or not it is included in the RIM conversation.

Figure 3: Cross Sector RIM Status (2014)

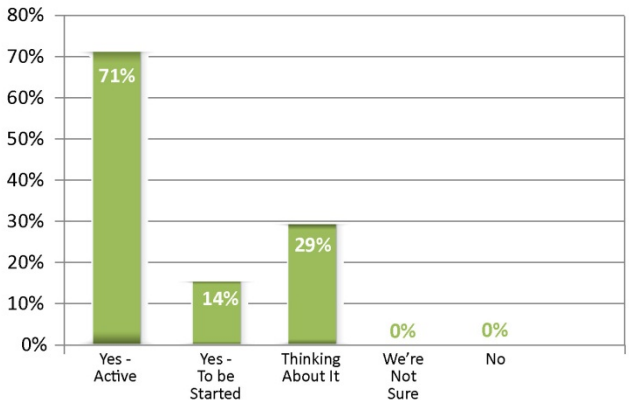
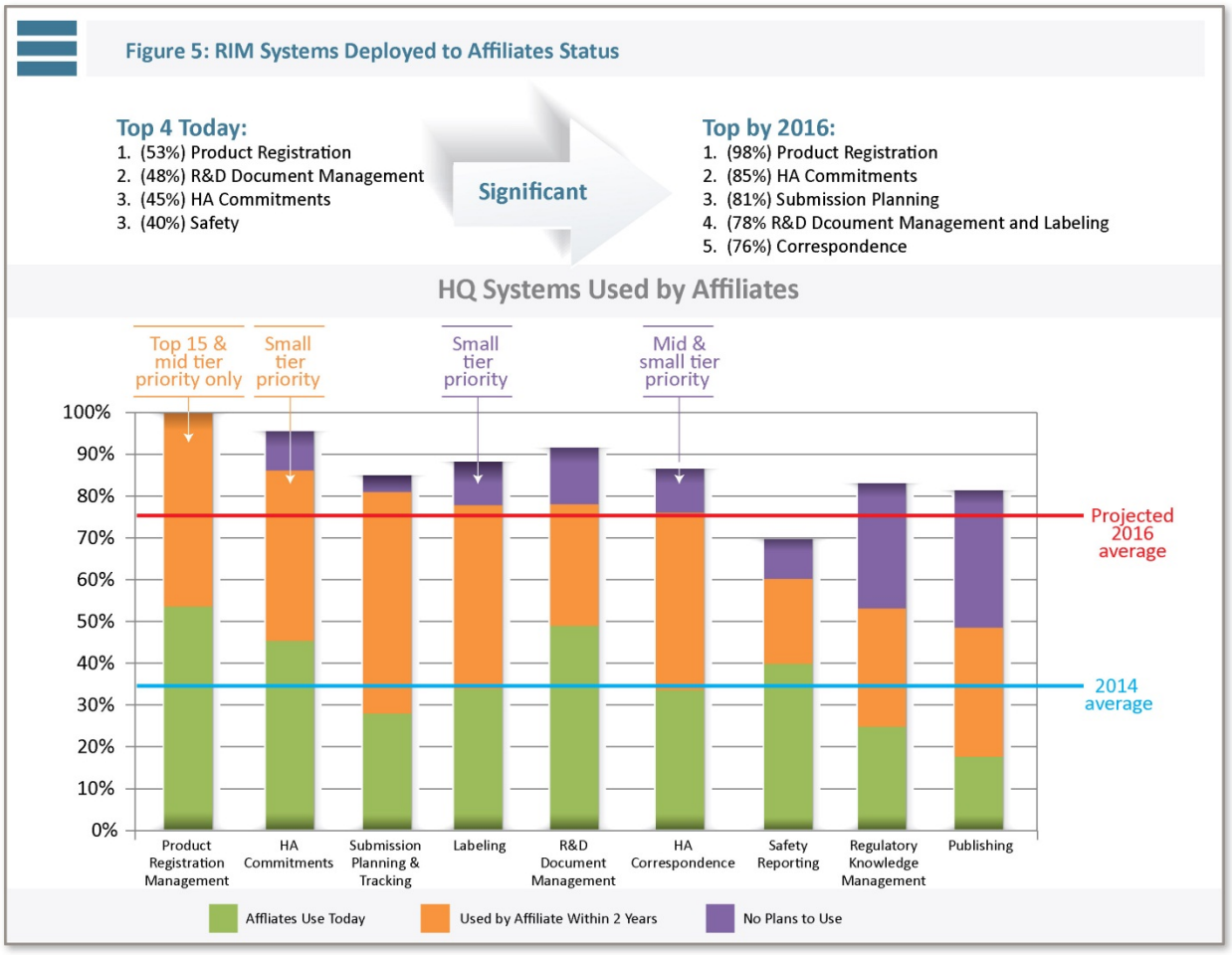


Figure 4: Cross Divisional RIM Consolidation Status

RIM Category	Utilize same tool/process	Planning to consolidate	No Standard tool/process and no plans to consolidate
Product Registration Management	75%	0%	25%
HA Commitments	50%	25%	25%
Submission Content Management	38%	38%	25%
Submission Plan and Track	63%	13%	25%
Regulatory Intelligence	57%	14%	29%
Correspondence Management	50%	25%	25%
Publishing	75%	0%	25%
Ad Promo	33%	17%	50%
Regulatory e Archive	50%	13%	38%
Labeling	38%	38%	25%

Another key focus area is the push of global RIM capabilities to the regional and local office. The planned investment in process work and system deployment is substantial as seen in figure 5. As many of you would suspect, product registration and commitments are deployed for about half of the participants. It is critical to note that the specific question looked for those who had at least 75% of their affiliates involved in that capability. For many companies, there may only be 10 – 20 countries involved today, but plans are to push this out much further. You can see the orange (used by 75% of affiliates within 2 years) is substantial with labeling, submission planning and tracking, health authority correspondence, product registration and R&D document management as investment focus areas.



The majority of companies are deep into their planning for IDMP compliance with just a subset of smaller organizations and several mid-tier delaying their gap analysis and strategy until later this year. What we find interesting is the significant difference between US and EU headquartered companies as to whom they include in the analysis, specifically for CMC/Manufacturing colleagues (see figure 6). We also see more educational struggles within US and Japanese headquartered companies relating to the management perception (a risky one) that IDMP compliance can be achieved manually at the last minute.

Figure 6: IDMP Stakeholder Analysis

Stakeholders Included	EU HQ	US HQ
Manuf/Supply Chain	76%	29%
MDM / Product Master	65%	35%

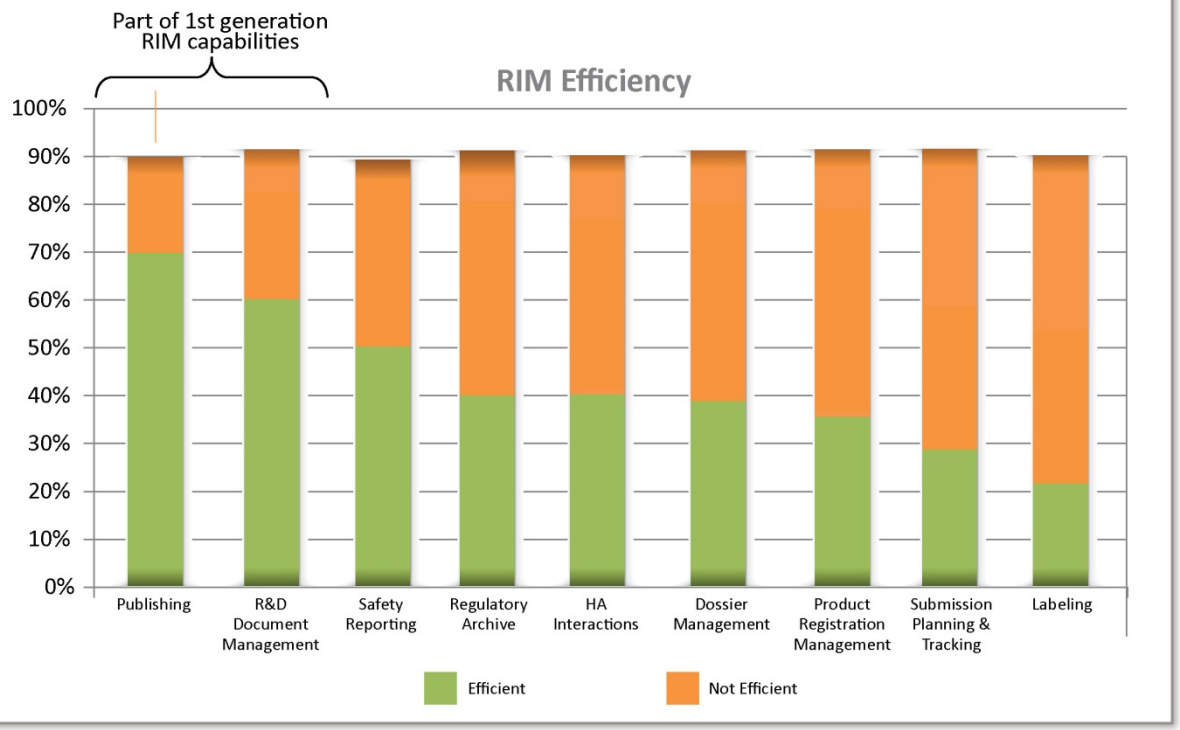
Finally, the general solution vendors are still in decline from an overall satisfaction level which is driven by significant usability challenges for the infrequent user (especially at the local affiliate level) and gaps in vendor innovation that have plagued this sector for 5 – 7 years, in our opinion. This theme will be explored in detail in the final section.

RIM Investment Priorities and Trends

We emphasized **efficiency** in many of the questions in this year's survey. In the past, the emphasis has been almost exclusively on being effective. Regulatory affairs and regulatory operations processes and best of breed technology were designed to be effective. The operational cost and effort required were secondary. For example, some companies employed Six Sigma principles, which stress quality and eliminating errors to achieve effectiveness. Today, a Lean Six Sigma approach is being employed to improve efficiency, e.g. reduction of duplicate data and processes, without losing quality.

The majority of companies rate themselves as efficient in only what we consider 1st generation RIM capabilities. Other critical capabilities, such as product registration management and submission planning and tracking, are rated "not efficient" in about 60% of the responses. Figure 7 shows the degree of perceived inefficiency for a subset of the RIM capabilities in the survey.

Figure 7: Efficiency by RIM Category



Improving efficiency is part of the rationale for a massive amount of change over the next two years with change in information standards, knowledge management and health authority interactions leading the way. Even relatively stable capabilities such as document, dossier and archive management are changing in at least 80% of the companies.

Improvements in data quality and tool usability are also common improvement targets. Except for daily users, who are presumably expert in the use of a system, RIM system usability ratings are almost

universally fair to poor. We see an increasing demand for software vendors to improve the overall user experience or at least provide "role based", personalized views of the subset of the information that is relevant for each person.

More than half of the companies in this year's survey view regulatory information management (RIM) as a strategic asset and a necessary part of the business infrastructure. This is a marked change from the recent past when RIM was more often viewed as a tactical capability to support submission production and filing, and to support compliance activities. In a separate pulse survey of 8 of the Top 15 companies, we found that at most have developed or are in the process of developing a cross-division regulatory capability. This form of strategic regulatory information management often employs a broader regulatory organization with the ability to deploy common processes, including governance, and technology to core regulatory activities across biopharmaceutical, medical device and consumer divisions.

In this year's survey, we asked for the top business priorities for the next 24 months. Four of the five most cited business "Top Priorities" can be considered global data quality and efficiency measures. Many companies are engaged in significant projects to improve product information and registration data quality. The most common top priority based on company size is:

- **Small-tier** top priority is to globalize key processes
- **Mid-tier** top priority is to realize more authoritative sources
- **Top 15** top priority is data quality, specifically for product registration capabilities

We also asked for the top RIM program technology priorities for the next 24 months. In this category, there is a wider distribution of technology priorities than business priorities but many of the top priorities complement the business priorities. For example, several of the most often cited top technical priorities support efficiency improvements, specifically:

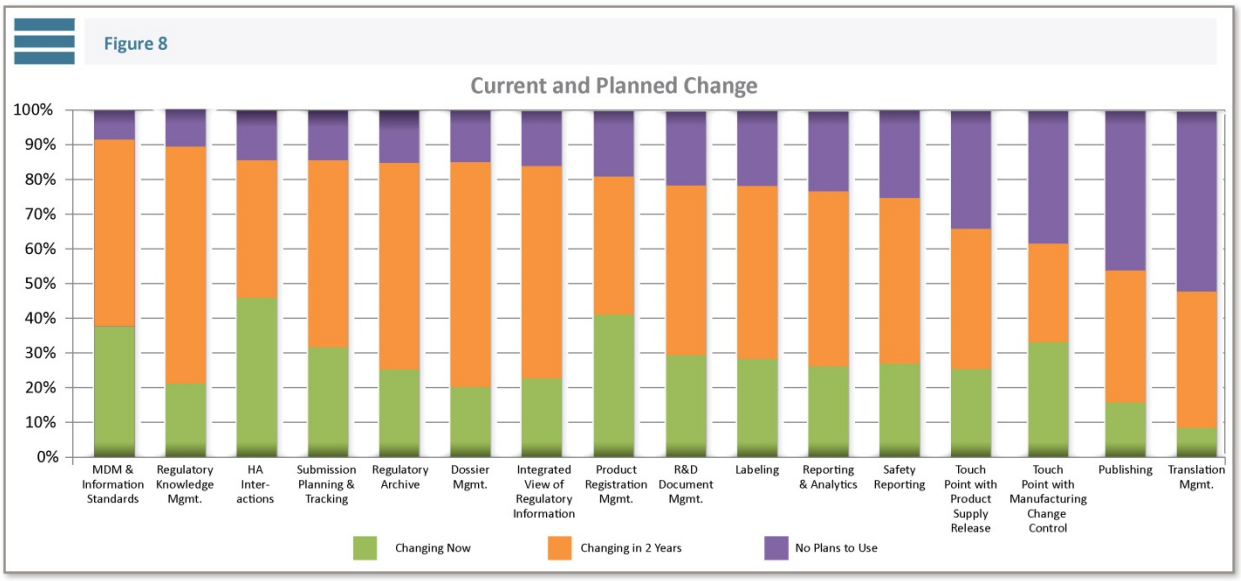
- Implementation of authoritative sources for regulatory information
- Improving affiliate / regional information access and improving system usability
- Providing an integrated view of regulatory information
- Improving search, reporting and analytics

Other IT priorities reflect current or future regulatory requirements, such as an IDMP platform and improved master data management. We believe implementation of data standards across regulatory and non-regulatory systems is being driven by the requirement to submit drug product information based on implementation of the ISO IDMP standards. This is discussed in more detail later in this paper.

We believe the emphasis on efficiency of regulatory information management, improving data quality and improving system usability will be the dominant drivers of change in the industry and for software and service providers for the next 1 – 3 years.

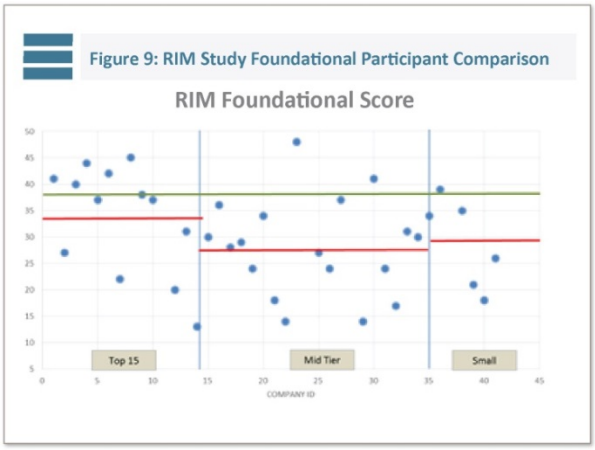
RIM Capability Update

A significant amount of change is forecast for the majority of RIM capabilities over the next two years. Figure 8 depicts which capabilities are currently undergoing change now (green), which are planned to be changed in the next two years (orange), and the areas where no changes are planned (purple). Product Registration investment along with Submission Planning continue to be high change areas with



Health Authority Interactions (Q&A and Correspondence) increasing in priority. We expected Master Data Management (MDM) and Information Standards to be a top change area due to XEVMPD and impending IDMP data standards. We were surprised to find the high amount of planned change toward Regulatory Archive and Dossier Management, although both were rated as 60% inefficient. The two areas getting the least attention are publishing and Translation Management as both tend to be stable and efficient capabilities.

We also ranked the 41 companies by their current and projected RIM foundation (see figure 9). This is comprised of the number of global authoritative sources, the effectiveness of the RIM foundation implementation, and their Regulatory Information Architecture (foundation for IDMP) status. Unlike the lower efficiency ratings, the overall foundation is a different picture with about half having a solid or emerging RIM foundation, and about 25 % having a significant amount of work to accomplish. The green line, in the graph, depicts our view of a solid RIM foundation level.



Product Information and Registration Management

This area has been getting significant attention and investment since 2009. The following were the key points from the 2014 benchmark:

- Many are rethinking their data entry / verification models with a preference for a data entry hybrid model (some affiliates enter directly while others send the information to a regional office or central organization for entry). Several participants are outsourcing this role.

Direct Data Entry Model	
Hybrid (Multiple DE)	26
Central ONLY	12
Regional ONLY	1
Local ONLY	2

- PAREXEL continues to be the market leader with dominance among the top 15, while the mid-tier market share is more distributed between PAREXEL, ArisGlobal, and internally developed systems
- Many of the solution providers are investing heavily to improve usability for infrequent users (e.g. local affiliate) and to prepare for IDMP compliance
- Product Registration is the RIM capability with the highest deployment to the local affiliate

Content Management (Submission, Controlled, TMF, and Label)

We combined these categories this year as the overarching theme from the research reflects the vast majority are starting to strategize and explore a simple question: what is "next generation content management"? We believe this is driven by a number of factors:

- Content Management systems typically have a 7 – 10 year life span due to the capital investment required and complexity of implementation; many are approaching this timeframe
- Supplier field has been relatively static over the past 7 years; however new solution sets by VeeVa and EMC D2 are changing the market dynamics along with several European niche providers
- Participants that have CSC, Customized Documentum, and Documentum DCM solutions have a higher than usual potential change percentage. Since 2007, we have asked: 1) What solution do you have, 2) Will you change it in the next two years, and 3) what is your satisfaction (5 point scale).
- Several suppliers are on the decline (satisfaction and innovation ratings)

Other 2014 Survey Salient Points

- Cloud based or software as a service solution is gaining traction
- TMF solutions providers are changing with Veeva, EMC D2, and Phlexglobal picking up market share

Submission Planning /Dossier Management / Publishing

Submission Planning was the top RIM change area in 2013 and 86% are either improving the capability in 2014 or within two years. We also see a substantial increase in those that are changing their Dossier Management practices and processes (83%). In our consulting experience, companies are looking at the combined workflow of submission planning, dossier management and publishing operation to drive out inefficiencies and improve resource productivity. We believe this is driven by three key needs:

1. Better submission demand forecasting to improve the global publishing operation productivity and increase the ability to perform simultaneous submissions to multiple countries/regions
2. Improved volume visibility for strategic third party dossier outsourcing partners
3. Better awareness of the volume and timing of label and CMC changes to support improved regulatory resource utilization at the local affiliate office

2014 Survey Salient Points

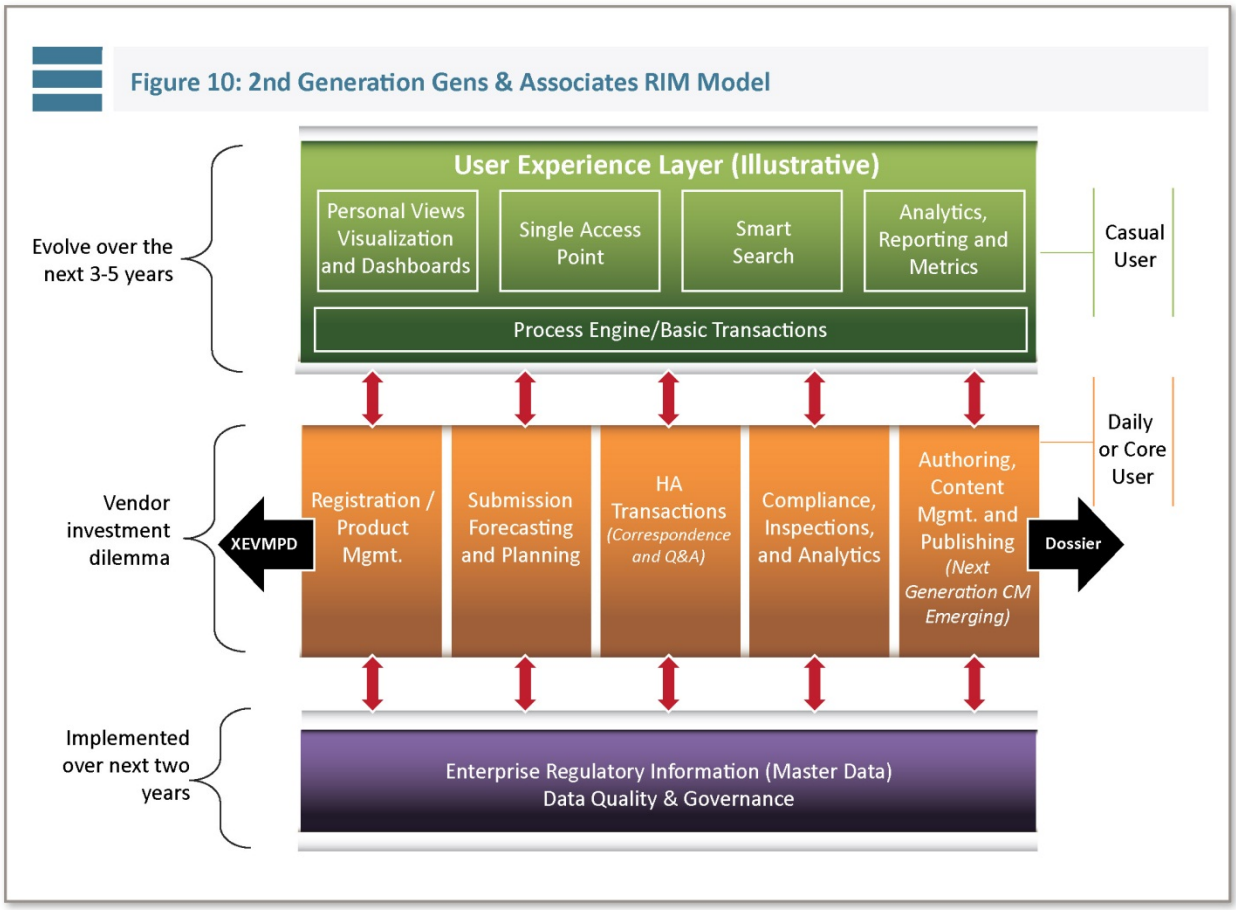
- eCTD software has the lowest predicted change in the next two years (16%)
- 13 out of the 14 Top 15 companies are either changing or plan to change their submission planning program
- 42% are planning to change their submission planning solution within the next two years

2nd Generation RIM: *A Point of View*

Since 2012, we have done significant client work surrounding RIM strategy, developing 3 – 5 year RIM roadmaps with associated business case, and local affiliate analysis in addition to our routine survey research. We felt in the summer of 2012 that the industry was at an inflection point, but just couldn't put our finger on the specifics. We explored this in our large early 2013 RIM study (n = 37) and found companies were looking at RIM more strategically and that multiple functions were part of the program.

We started structuring our views in 2013 and began using this model (see figure 10) in our client work and speaking engagements. Several of our 2014 research questions tested some or our assumptions surrounding usability, solution set innovation, and degree and timing of change. We feel our model has proven to be sound and will be the basis for RIM for the next 5 - 7 years. The model contains three layers: usability, solution sets, and information architecture. The solution set layer has been in place for most companies since the early 2000's and has grown and evolved in step with the solution provider pace of change (not industry's pace of change!). The 1990's saw the emergence of electronic submissions that fueled first generation document management and publishing solutions which were typically implemented by integrators and consultancies. The 2000's saw a change to the solution providers driving the implementations and RIM conversation.

Figure 10: 2nd Generation Gens & Associates RIM Model



Today there is a clear usability gap, especially for the infrequent user where our model begins. We envision not only access by role (landing page or portal type of architecture), but conducting basic transactions outside the native application. For example, imagine you're a regulatory affairs professional in Brazil and just got your product approved. Instead of going into your local Excel tracking sheet, the global product registration system, the global content management system, and the regional Sharepoint, you would simply go to a product page and change the status to "approve" and add the approval letter URL. The system would then place it in the proper operational systems. The native applications (product registration, document management, correspondence etc.) would be used by the full time operational people or those using the system for a significant portion of the time. Some of our clients are already piloting such concepts with the help of an integrator pairing with the native application solution provider. We believe this will become mainstream in 2 – 3 years.

The bottom layer is being built now due to the growing data standards, especially IDMP (we have a section dedicated to the information standard topic). As companies invest in master data management programs that will allow a much easier and cost effective approach to data exchange (internally and externally), the benefits will be substantial. This will directly impact the green or usability layer in the form of aggregate reporting across solution sets and fully achieve an "integrated view of RIM information"

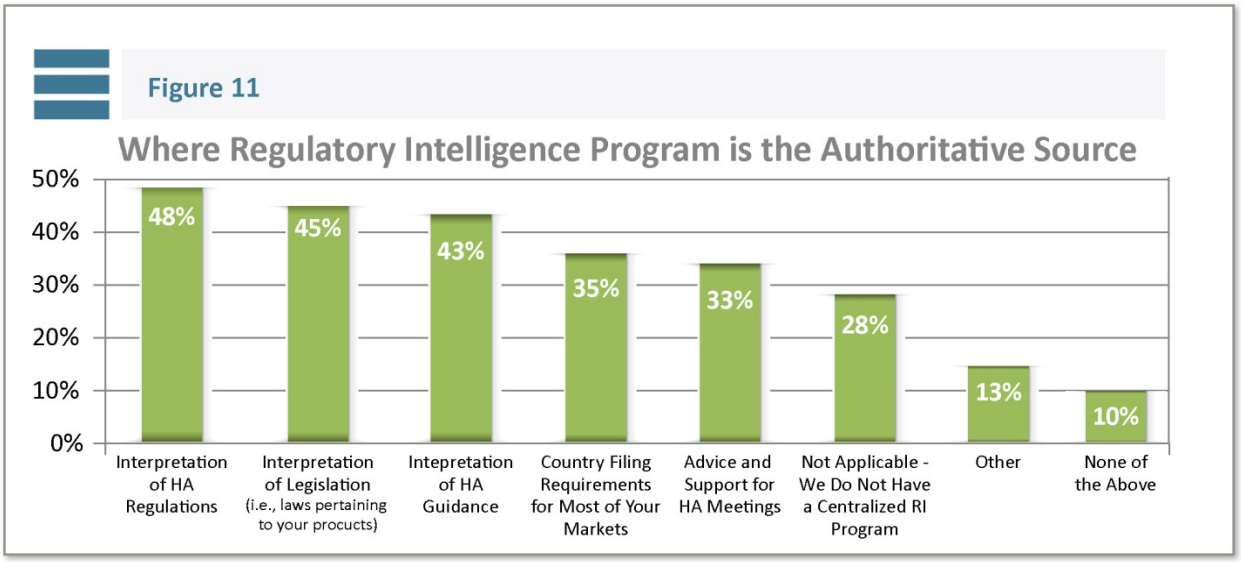
Regulatory Intelligence (RI)

Providing timely and authoritative regulatory intelligence is a challenge for companies of all sizes but, is particularly challenging in large and mid-tier companies with products in many markets. Regulatory intelligence groups are expected to deliver an authoritative interpretation of a wide range of national and regional regulations and to provide an impact assessment of proposed regulatory changes in many more markets than in the past.

There are several factors that make this increasingly difficult for central regulatory intelligence groups:

- If there is a central RI program, it is usually made up of a relatively small headquarters staff, located primarily in the company headquarters with possible additional staff in a major market
- The mission of the central RI group is often relatively broad. This makes it difficult to define the priorities and true scope of the group. Small staff and broad mission leads to misunderstanding of the group's role among stakeholders (customers) and the staff themselves, resulting in reduced effectiveness. The diversity of the mission is illustrated by the need to provide services that cover both "hard" and "soft" intelligence. For example, what are the specific clinical endpoint requirements for a country's population (hard intelligence)? And what are the lessons learned from meetings and informal contact with regulators (soft intelligence)?
- The increasing requirement for information and inspections by Health Authorities that once accepted product approval by a reference country as the primary requirement for marketing approval

We have found that customers place high value but low satisfaction on the products of the RI group. To meet the challenges, 67% of the companies in the 2014 survey have established a centralized regulatory intelligence office or program. However, when asked if the centralized RI program is viewed as the authoritative source for various hard and soft intelligence services, fewer than half responded "yes" for any of the services (figure 11). This includes core RI services such as interpretation of laws, Health Authority regulations, and guidance. And only 1/3 responded that their RI program is the authoritative source for advice and support for Health Authority meetings.



In some cases, the low number of companies reporting their RI group as the authoritative source is due to the need to use other internal experts to produce a complete analysis and official company position on regulations or guidance. In other cases, stakeholders in need of regulatory intelligence fall back on their own internal networks and external sources to develop an opinion and action plan to meet new regulatory requirements.

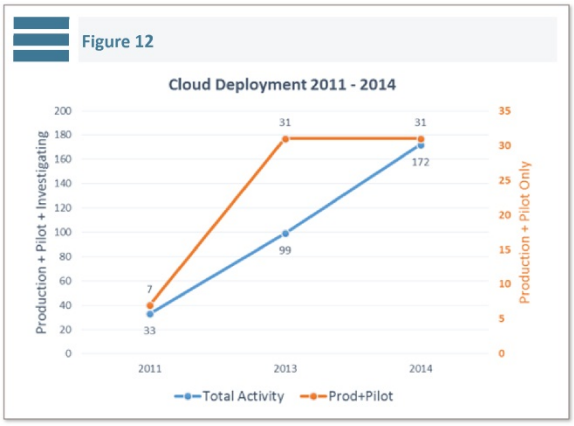
About half of the companies are changing their programs within the next two years, especially in the mid-tier companies. We assume the changes are intended to provide better and more complete regulatory intelligence through central programs. Virtually all companies making changes are planning change in:

- **Processes** – frequently this centers around improving internal communication among the central group, regulatory affiliates and functional areas to ensure there is two way communication among all groups
- **Regulatory information management tools** – these are designed to provide improved access to curated information through information portals, knowledge management systems and expanded external tools
- **Program scope, roles and responsibilities** – these organizational changes are aimed at the key problem of identifying the true mission and value of the group and improving delivery thus increasing stakeholder satisfaction

Regulatory Capabilities in the Cloud

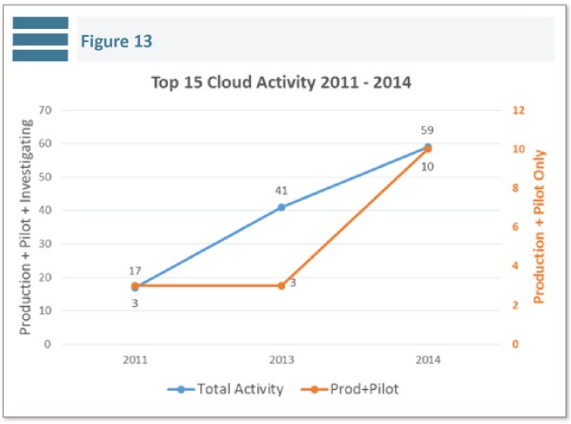
We have been monitoring interest in using cloud infrastructure and cloud based software, also known as Software as a Service (SaaS), since our 2011 survey. At that time there were very few companies investigating cloud for regulatory capabilities and even fewer with pilot or production instances. The blue line in figure 12 shows the total number of regulatory capabilities for all companies in our surveys that are in production, in pilot and being investigated. This number increased significantly in 2013 and again in 2014 with over half of the participating companies investigating at least one cloud based regulatory capability. The orange line shows production and pilot deployments over the same time period.

Figure 12



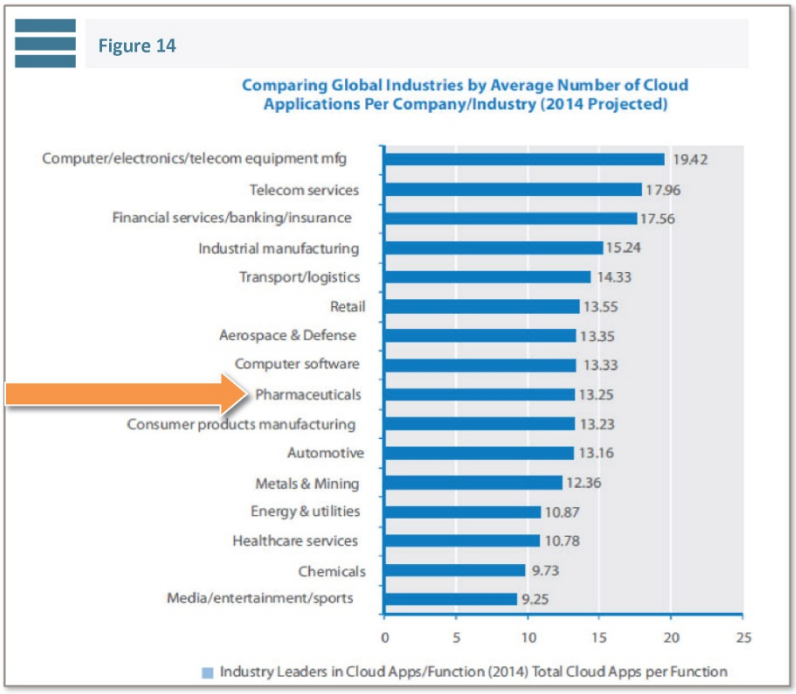
The total number of capabilities in production and in pilot leveled off between 2013 and 2014. However, when the Top 15 companies are examined separately (see figure 13), the orange line shows a sharp increase in the number of production and pilot deployments. Although the total number of deployments is still small, this could be an indication that the companies, especially among the Top 15, will be deploying an increasing number of cloud based capabilities in 2015 and beyond.

Figure 13



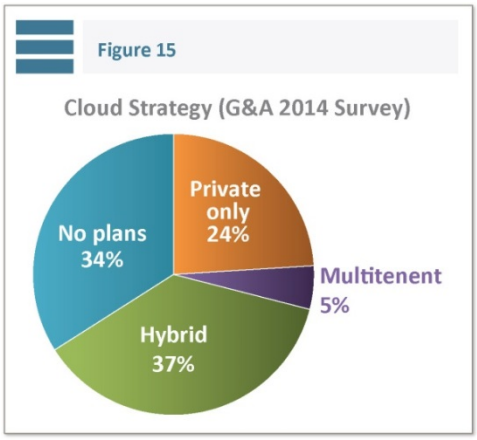
Our survey data is consistent with other industry studies (see figure 14), which project the pharmaceutical industry to have about half the number of the cloud applications in 2014 as the top cloud users among global industries[1]. This projection includes all capabilities as well as regulatory.

Figure 14



[1] The State of Cloud Application Adoption in Large Enterprises, TCS Global Trend Study, March 2012

In addition, we find the majority of companies that are using or investigating the cloud for regulatory capabilities prefer a hybrid model (37%), followed by a pure private cloud (24%) (see figure 15). In contrast, according to a general industry survey for global industries[2], 74% have a hybrid cloud strategy and only 9% prefer a pure private cloud strategy



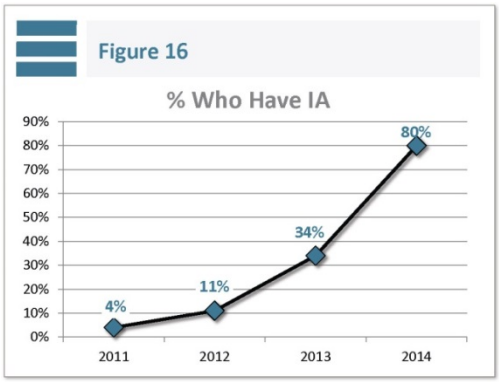
Although there is slow adoption of cloud based capabilities, more than half of the companies in our survey expect improvement in many key performance indicators when a cloud solution is deployed. This is confirmed by 7 of the 8 companies that have 6 months or more with a cloud RIM capability. In this set of companies, at least half reported improvement in key areas including:

- Time to implement
- System Availability
- Cost

We expect continuous growth in the number of cloud deployments and an increase in the number of regulatory capabilities deployed in the cloud. A combination of private and public cloud deployments is most likely as security, regulatory and legal liability issues are sorted out. The experiences of other industries will continue to provide precedent for moving mission critical, regulated and company intellectual property to the cloud.

Information Architecture / Standards Initiatives and Adoption (IDMP)

The growing investment in information architecture and information standards is being driven by the convergence of master data management, information sharing requirements for global affiliates and external partners, and evolving Health Authority requirements, most recently IDMP.



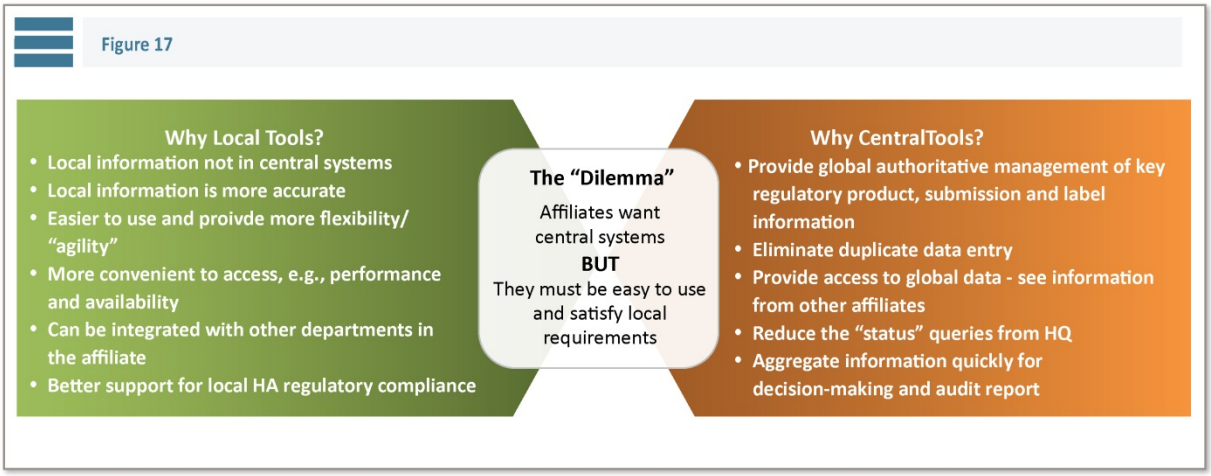
Some companies are leveraging IDMP requirements to provide additional support to the information architecture business case. In figure 16, note the sharp increase in the number of companies planning on having an information architecture in place for regulatory information by 2016. It is possible that IDMP requirements will now help fund what have been underfunded information architecture and data

[2] RIGHTSCALE 2014 State of the Cloud Report

standardization programs historically. The goal of information architecture programs has been to provide an end to end regulatory information management capability that supports "horizontal" and "vertical" information access and standardization. The horizontal requirements are driven by the need to combine information from regulatory, therapeutic areas, clinical, manufacturing, and external partners. For example, we see that more than 65% of the companies will include safety, clinical and manufacturing in their regulatory information architecture program. Without information standards to define the information and agreement on format and content, effective information sharing and aggregation will continue to be difficult and labor intensive.

The vertical requirements are driven by the need to share information globally, within the enterprise. This includes headquarters functions, regional regulatory and operations, and local affiliate offices. We have found a strong desire among affiliate staff to use central information and tools in order to be more efficient. However there is a need to ensure those tools can be used and meet the needs of the affiliates. This is the dilemma described in figure 17 which is based on our work with a number of large pharmaceutical companies.

Figure 17

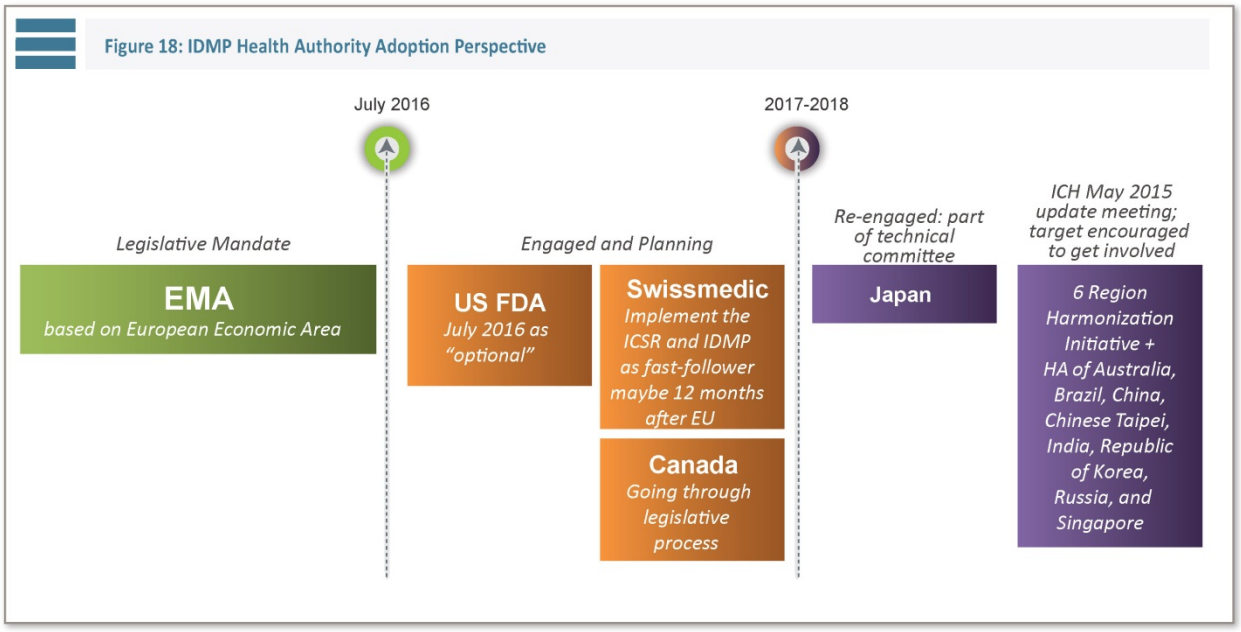


A true and effective authoritative source for each core regulatory information element is a requirement. Many company authoritative sources are "aspirational". In other words, there are systems that are designed to be the authoritative source but there are still many duplicate information sources for information both at the headquarters level and in affiliates. The 2014 survey shows over 80% of the companies plan to have a true authoritative source all major RIM capabilities.

In the area of IDMP compliance, most companies are engaging stakeholders beyond regulatory. However, most also report major challenges to IDMP projects including challenges obtaining budget, overcoming unrealistic management perceptions and educating stakeholders. The latter challenge is most common among United States headquarters companies.

Many companies are just starting IDMP strategy and data analysis projects with the hope of finishing data identification and collection into an initial IDMP submission by the mid 2016 deadline. This is likely to be a major challenge for large and midsize organizations given the large number of information

sources, including unstructured sources, and the lack of systems that support the IDMP data model and IDMP submission process. In addition, there is a lot of work to be done to implement a sustainable and repeatable IDMP submission program that can be scaled up to support submission to more Health Authorities (see figure 18). How can short-term investment and architecture options be made strategically to avoid waste is a key question, especially for the mid-tier and top 15 companies.



We believe a two phased IT strategy is most appropriate. Phase 1 is to put in place a preliminary set of technical tools and manual processes to collect and standardize the information from structured and unstructured sources. Then build and transmit the IDMP submission.

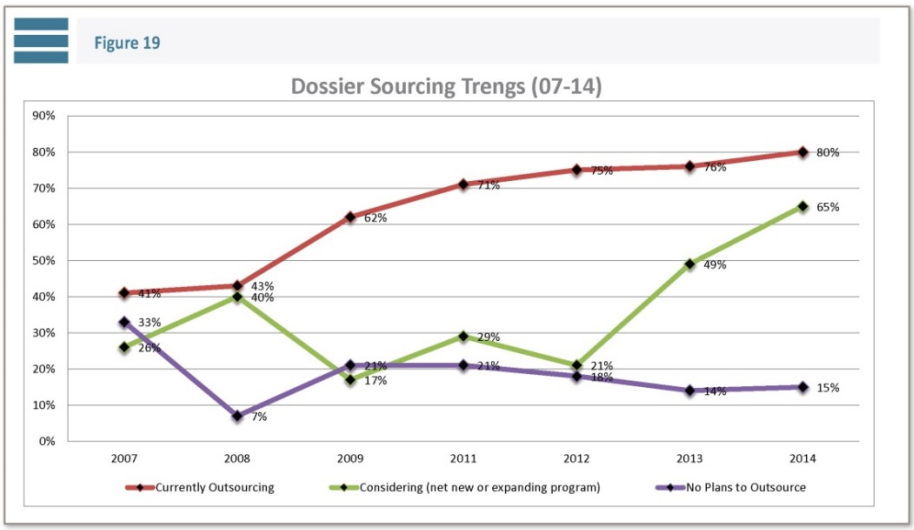
Phase 2 extends data standardization to many, if not all, of the contributing systems, thus simplifying the data transformation and cleanup activities for subsequent IDMP submissions. This also requires a robust, cross functional governance program to ensure standards are maintained and updated as each of the contributing systems evolve. In addition, regulatory systems should be upgraded to support the IDMP data model and the submission process

Implementing and operationalizing processes, systems and governance is critical to meeting current and future IDMP, and other evolving regulatory submission requirements.

Outsourcing Status, Trends, and Supplier Summary

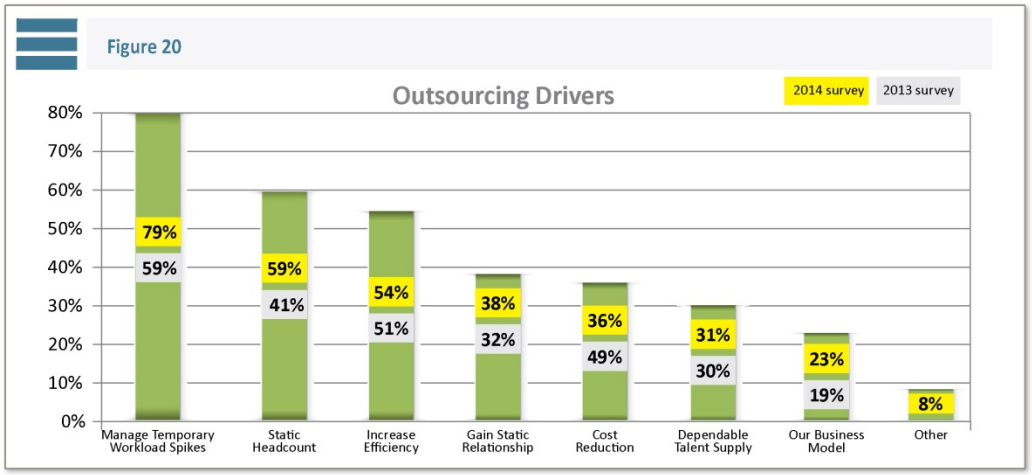
We have tracked dossier outsourcing since the inception of our industry benchmarks in 2007. There has been a gradual increase in the use of dossier outsourcing (see figure 19) since the tipping point in the 2008-2009 timeframe, and in 2014 we now consider it a common practice. There are many qualified suppliers with very positive satisfaction ratings and a variety of viable outsourcing models ranging from individual application types to full function outsourcing.

Figure 19



The primary business driver is shifting as well from primarily a cost reduction benefit in previous years for large multi-nationals, to more management of organizational headcount and workload levels as described in figure 20. We still see cost reduction as a significant driver for top 15 companies (43%) compared to their mid-tier and small company counterparts. While we didn't ask a survey question surrounding changing roles, our client work finds many organizations espouse to refocus their senior publishing headcount into higher internal value roles such as dossier management, submission forecasting / planning and strategic supplier management.

Figure 20



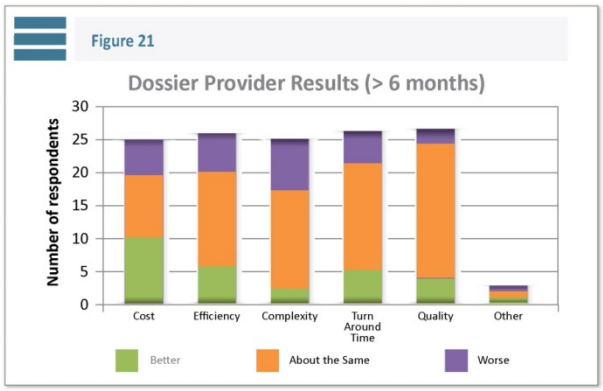
We first started tracking overall dossier satisfaction levels in 2011 and they continue to have strong positive ratings. Our fall 2014 study quantified for the first time the supplier field; who are primary and secondary providers and their associated satisfaction ratings. The supplier field is growing due to: 1) a high addressable market (~ 700 million dollar market over a 5 year period – our 2012 study) and 2) the push to more strategic relationships that can cover all submission types and geographies. We believe the supplier field can be segmented into several categories:

- **Traditionalist:** PAREXEL (old Liquent), Accenture (old Octagon) , and CSC (old ISI)
- **India Based Outsourcing:** TCS, Cognizant, and TAKE
- **Regional Players:** Kinapse, Product Life Group (there are many others we do not track)
- **Contract Research Organizations (CRO):** Quintiles, PPD, and PAREXEL (prior to Liquent acquisition)

The CRO emergence, we believe, is driven by more countries requiring clinical development for market authorization which makes CTA outsourcing an attractive option (CRO completes the regulatory matter). They also have the local country regulatory intelligence expertise (country filing and product strategy).

The India based outsourcing primary benefits are efficiency and cost with extensive high volume transaction outsourcing experience in information technology, clinical and safety case reporting.

We also collected data in 2014 from those with at least 6 months of dossier outsourcing experience (see figure 21) which shows a picture of mature processes and solid business benefits. We view both the green (better than internal) and orange (about the same as internal) ratings as positive. We conducted analysis by size of company and found the top 15 benefits mostly from better cost as compared to the mid and small tier while all other categories had a fairly equal distribution among size of companies.

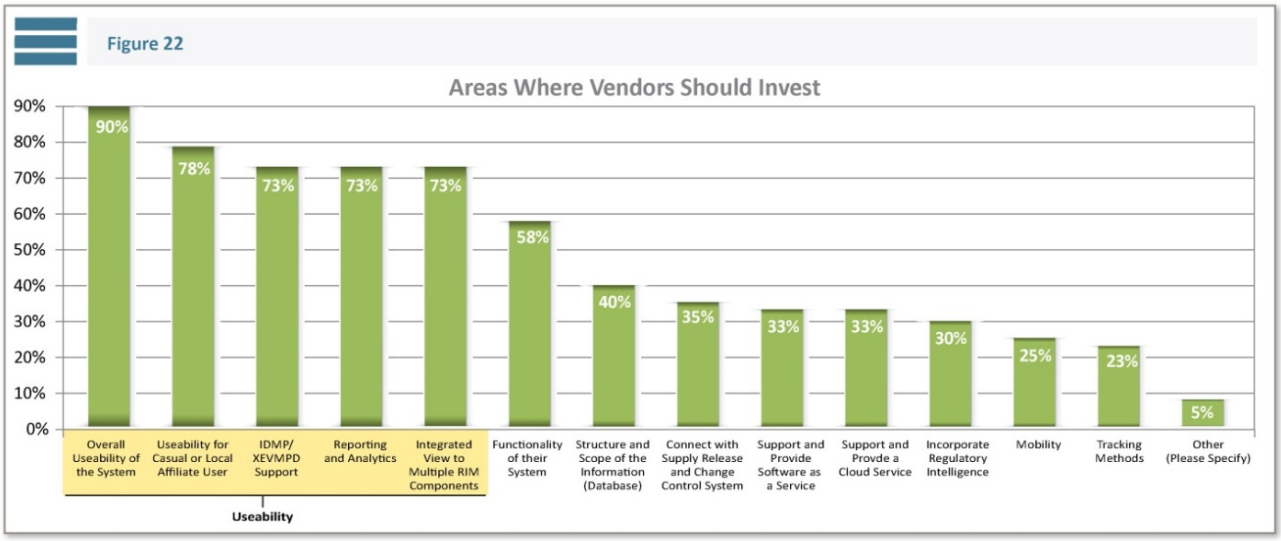


Finally, we asked our 2014 study participants to rate other areas of regulatory outsourcing and learned the following: (% that are outsourcing today / % are investigating to outsource in the next two years)

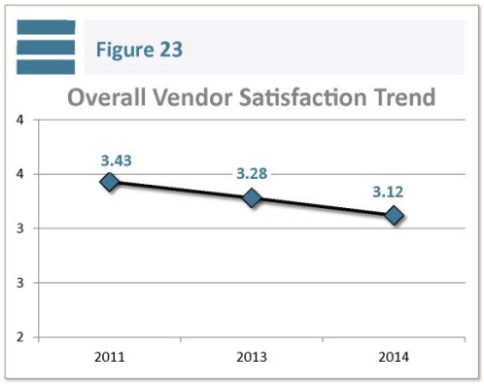
- Safety Reporting (40/10)
- Registration Data Entry / Verification (28/20)
- XEVMPD Data Entry / Verification (30 /15)
- Dossier Management (25/5)
- Country Filing Requirements (13/15)
- Commitment Management (15/8)

VENDOR LANDSCAPE: INNOVATION, MARKET SHARE AND SATISFACTION RATING

In 2013, we stated "the pace of industry change is greater than the ability of the solution providers to innovate and this is a growing challenge". We explored this theme from three angles: 1) what are the most important areas for the RIM vendors (generally) to innovate and invest, 2) what is the solution provider (as an aggregate) satisfaction trending over time and 3) which solution providers are



innovating, stable, or declining. The priority investment result (see figure 22) was no surprise as four out of the top five are related to usability. This is particularly acute with infrequent users (78%) that are either basic consumers of RIM information or do sporadic entry of limited information such as changing a registration status code (product approved with a linked approval letter in the content management system). We also consider reporting / analytics and an integrated view to multiple RIM components as usability challenges. Reporting tends to be complex especially in Product Registration and Submission Content Management systems and the ability to aggregate information across RIM components is an extreme challenge for most. There is a growing need to achieve an integrated view of RIM components that we discussed extensively in the 2nd generation RIM section.



The second area concerning the innovation gap is declining overall satisfaction ratings (see figure 23). We have been collecting market share and solution provider satisfaction data regarding submission content management, product registration, submission planning, eCTD publishing, labeling, and trial master file since 2007. We use a five point scale with 3 being "neutral" and 5 being "very satisfied". The overall 2011 score was strong and has been declining ever since. While the majority of the solution providers have declining marks, there are several instances of stable satisfaction ratings and several providers that consistently have strong ratings. We

further dissected this information by RIM category (see figure 24) to understand satisfaction trends. Product Registration capabilities have the lowest ratings with Health Authority and Submission Planning/forecasting at the low end as well. Both Labeling and eTMF providers enjoy the highest scores.

Figure 24: RIM Capability Satisfaction Level Trending

Set		Average Satisfaction (0 – 5 scale) 2014	2013	2011	Predicted Solution Change Within 2 Years
HA Interactions	(n)	3.0	3.0	No data	20%
Registration Management	(↑)	2.9	2.7	3.0	46%
Submission Plan/Track	(↑)	3.0	2.9	3.3	42%
Submission EDMS	(n)	3.2	3.3	3.6	33%
eTMF	(n)	3.3	3.4	3.3	30%
Labeling	(↓)	3.4	3.6	3.4	24%
eCTD Publishing	(↓)	3.1	3.5	3.7	16%

n= neutral or insignificant movement

> or = 3.5 | 3.0 to 3.4 | < 3.0

We also summarized the solution sets by predicted change within 2 years. The data clearly shows the potential of market-share change in the registration management, submission plan/track, submission EDMS, and eTMF categories. This aligns well with the data surrounding top RIM business and IT priorities in the next two years. We were initially surprised with the dramatic drop in satisfaction of the eCTD publishing category as the history shows high satisfaction levels; as we looked into the details, this was due to a significant reduction of one of the major eCTD publishing providers.

A new question in our vendor landscape section was “perceptions of innovation” with a sampling of 19 providers (see appendix for provider sample) ranging from large multi-sector players to small niche or regional providers for Life Sciences only. Innovation is a relative term as it can mean different things to different teams. Our question surrounded perceptions of these 19 providers; who is innovating, who is stable or just “evolving” their RIM capability, and who is in decline. The results were telling of the sector as a whole. Only one supplier received high innovation marks, 12 were rated as stable, but not innovating, and the remaining 6 were rated as declining. We conducted secondary analysis on our demographic data and found significant perception differences based on company size.

We believe the core issues for the innovation gap are multi-dimensional:

- Most providers have a “step” approach to solution enhancement (e.g. what additional features/functions are required)
- Usability is a core challenge in the “download a simple app” era
- Solution provider software is geared toward the very experienced operational user, leaving the infrequent user frustrated (overly complex to use)
- Many solution providers struggle with the required capital to overhaul aging solutions without a clear revenue path or attractive addressable market figures
- Little competition has left this “niche” area under-invested by the majority of the solution providers

Finally, many providers are making significant investments to improve the usability of their solutions in parallel with realizing the positive impact of data standards (e.g. ISO IDMP). Our analysis predicts that within 2 – 3 years, many of the glaring challenges will be filled and we hope the satisfaction ratings will progress to a positive trend. We regularly request briefings from many of the providers to understand their status and investment priorities. Please contact us if you would like specifics about individual providers.

White Paper Authors

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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*
25) 2015 Next Generation Content Management (In Design)

16 RIM Categories

1. Submission Planning and Tracking
2. Product Registration Management (full product lifecycle)
3. R&D Document Management
4. Publishing (assemble and publish)
5. Dossier Management (content plan, distribution, archive)
6. Health Authority Interactions (Commitments, Q&A, Correspondence)
7. Master Data Management and Information Standards (IDMP, xEVMPD, etc.)
8. Regulatory Archive (regulatory submissions and supporting documents and information)
9. Labeling (core data sheet, change control, status tracking, etc.)
10. Safety Reporting (PSUR, DSUR, RMP, RMP lifecycle, etc.)
11. Manufacturing Change Control (methods and spec's)
12. Product Supply Release (including export / import tracking)
13. Translation Management
14. Regulatory Knowledge Management
15. Integrated View of Regulatory Information
16. Reporting and Analytic

Providers in Innovation Rating (sorted alphabetically)

1. Accenture / Octagon
2. ArisGlobal
3. CSC/ ISI
4. EMC
5. Extedo
6. Glemser
7. Global Submit
8. IBM
9. Infotehna
10. Lorenz
11. Microsoft
12. Mission 3
13. NexDocs
14. PAREXEL/Liquent
15. Planisware
16. Samarind RMS
17. Trackwise
18. Veeva
19. Virtify