



DIA Regulatory Affairs Community Regulatory Information Management (RIM) Working Group

RIM Framework Interim Consensus Paper

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Abstract

The Regulatory Information Management Working Group (RIMWG) of DIA's Regulatory Affairs Community has identified potential benefits that could be captured from the development of a conceptual framework for Regulatory Information Management (RIM). Such a framework would aid organizations in structuring the complex organizational, informational and technological issues germane to RIM's myriad of challenges related to cross functional global data identification, ownership, quality management and maintenance. The ultimate goal of these efforts is to enable RIM to be a strategic corporate asset that will have direct impact on a sponsor's profitable operations and, ultimately, expediting delivery of needed treatments to patients. This Consensus Paper chronicles the evolution of the RIMWG's discussions, debates, feedback and decision making by varied global RIM stakeholders during development of the framework. The framework itself is comprised of the "RIM Elements" catalog (in process), which defines RIM according to common themes, or "buckets", and a data map (in process) that identifies data elements and determines how data flows through the organization and related systems. The key objective of this initiative is to define an "Ideal RIM state" along with a RIM Reference Model made of a collection of data, process and organizational constructs which could be used as a benchmark for both sponsors and vendors to compare their capabilities and offerings respectively. Together the collection of data and process flow recommends not a binding regulation, but rather a reference-able framework for that "Ideal RIM state" upon which organizations can begin to model and benchmark against. The intention here is to create a framework which could benefit sponsor organizations, as well as technology and service providers in their effort to improve how we manage regulatory information.

Keywords:

Regulatory Information Management, Data governance, regulatory data quality, regulatory systems

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1. Introduction

Organizations engaged in development within life sciences face an increasingly challenging environment: an expanding global footprint, evolving regulatory requirements, dynamic partnership models, and rapidly evolving technology. At the same time, many organizations are also innovating how regulatory data is captured and utilized, navigating the GxP and collaborative ecosystems that are commonly referred as RIM.

Organizations, both sponsors and the vendors that serve them, have come up with organic solutions that are fit for specific purposes; however, oftentimes the resulting bespoke systems are not harmonized in approach or terminology which compounds the complexity associated with ownership, flow of data across the enterprise, interoperability, quality responsibility, and governance of regulatory data, or any form of collaboration.

Moreover, organizations are making enormous investments in technology solutions in silos — systems that serve specific purposes but don't easily allow the flow or communication of common data elements to or from other silos. They allocate tremendous hours and labor to keeping these systems up to date while protecting the privacy of patient data and value of corporate data from external threats. Between the building of the datacenters and the maintenance of all these systems, they barely, if ever, have an opportunity to capitalize on the wealth of information that data represents as a corporate asset. As consumer organizations and private companies start to capitalize on the use of data to enhance their business in myriad ways, the global pharmaceutical, biotech and medical device sectors are starting to look at data as having a major and quantifiable potential impact on improving operational efficiency and data security.

Efficiently managing this complexity could be greatly enhanced by a unified description of an “Ideal State” of RIM, in terms of harmonized definitions of common processes and concepts, systems used, data entities, master data, and governance structures. This ideal state is unlikely to be achieved in full in actual practice, as many initial RIM approaches have already been implemented. In some cases, these approaches are, if not truly mature, individually entrenched, and are now causing companies to think about integrated solutions. However, as RIM evolves, and the pressure increases to understand the data in regulatory and clinical planning more accurately and sooner, any improvements can transform RIM into a commercially impactful asset unlike regulatory has ever been able to achieve in the past. Truly, information is power. The potential benefits of significantly improved RIM are legion.

2. Initial Development of a Vision and Outline for a RIM Framework

The RIM Working Group's (RIMWG) genesis was at an “Ask the Experts” Panel at the May 2015 DIA eRegulatory and Intelligence conference. The discussion revolved around the unprecedented success of the DIA Trial Master File (TMF) Reference Model, the main deliverable of the TMF Working Group in the DIA's Document and Records Management Community. Parallels were drawn between RIM today and TMF's disorganized and problematic status when it started in 2008: both are critical to the efficient, effective work being done, but not directly related to regulations or submissions – which has been the primary driver of regulatory technology solutions to date. After the session, several participants including Sheila Mahoney-Jewels and Peter Terbeek (Terbeek and Mahoney-Jewels, 2017) co-founded the nascent RIM working group with the goal of replicating the TMF Reference Model's extraordinary self-organizing state of 2015.



The initial goal was to develop a RIM Reference Model but the group quickly decided that was too ambitious. Like RIM, TMF lacked agency guidance, however still had far more traditional structure than the wide-open space of RIM. The initial meetings were comprised of a small number of sponsor companies and service providers that were passionate about improving RIM for Industry. Within a few months of the conference, the group transformed to a Working Group, with the intention of identifying specific deliverables over time.

For several months, during its early formation period, the group attempted to be part of the IRISS Forum or one of the Regulatory Affairs Communities under DIA. During this time, the Working Group did not widely advertise additional participation beyond the initial 5 or 10 regulatory participants, due to the need for greater organization and ability to mobilize wider membership. Also, during this time, the group drafted an initial Charter, and began to identify potential deliverables of the WG. After several months of these foundational activities, a group vote was taken to decide that the Working Group become part of the DIA. This was due to:

- DIA's greater size, ability to reach greater numbers of more diverse types of regulatory professionals (membership over 10,000, vs. IRISS' approximately 4-500).
- The WG's closest inspirations and experiences resided in DIA, namely the TMF Reference Model and Electronic Document Management Reference Model.
- Whereas IRISS' main, and significant, attraction was its responsiveness to its members, its focused attention and impressive support tools, the WG felt IRISS' core focus on submissions and implantation of supporting systems was too restrictive for RIM, which, though related, is a much broader topic. The DIA's RAC already had several long established and productive Working Groups such as Regulatory Intelligence and Labelling which were both complimentary to the RIMWG goals and potentially mutually beneficial.

2016 saw the RIMWG's deliverables come sharply into focus:

1. RIM Elements Catalog: Basic definitions of main components or business capabilities recommended to move towards leading practice "RIM", broken out by the following individual but closely related topics:
 - Publishing & Submissions
 - Labelling
 - CMC
 - Product Registration Management
 - Regulatory Intelligence
 - Cross-functional Touch Points
 - Others

This also sought to identify common related systems, as well as data ownership/governance/consumption. The goal of RIM Elements was not to create a binding definition, rather an "ideal state" recommended by the WG, and thus become a clarification tool to help regulatory professionals implement sensible changes and move towards the ideal state over time. The ultimate objective of the RIM Elements catalog is to define a RIM Reference Model as a guide to both sponsors and vendors to adhere to some common terminologies and business/system capabilities.

2. **Data Curator:** The term “data curator” emerged and resonated with the group. The curation of data seems to have landed in the hands of Regulatory, as they are the final step in the innovation, development, safety and compliance processes for the industry. RIM data input is not a static event, rather a living entity that accumulates in small amounts over time. Ensuring the ability to accurately input and maintain data over time and wide groups of geographically diverse users is critical for maintaining data integrity. At present, the “ownership” of data accuracy is another area that is not harmonized, understood, or addressed across most organizations as efficiently as needed.
3. **RIM Data Map:** Originally thought of as part of the RIM Elements catalog, the group identified the need for a data map to not only identify common RIM data elements but how they should flow through systems and curators, as well as where each should sit, organizationally, in the “ideal state”.
4. **Consensus Paper:** Documentation of the discussion/debate and decisions that inform the RIM Elements catalog and the RIM Data Map. The group realized that the “ideal state” the first two deliverables sought to describe would most likely not match any organization’s actual reality, perhaps not even close. The issues addressed were so complex it might not be obvious to the non-RIMWG participant how the group arrived at certain conclusions. It was imperative to document the evolution of decision making for posterity, to truly inform the RIM Elements and Data Map with foundational, understandable information and decision points.

3. Methodology

The RIMWG meets monthly via teleconference and cycles through topics across Regulatory. It is a participant-led meeting, seeding the discussion with pertinent questions related to each topic. The group then debates each question and, ideally, arrives at a unanimous conclusion. This white paper is an interim deliverable of such a collaboration. The ultimate goal of this working group is to define the RIM Elements catalog and/or Data Map which will become part of the RIM Reference Model.

4. What is Regulatory Information Management (RIM)?

Regulatory Information Management means different things to different people. As part of harmonizing the terminology and defining standards, the first order of business for the RIMWG is to define RIM. Regulatory Information Management refers to the effective and efficient identification, collection, curation, communication and management of regulatory information for products across the life sciences value chain. At a high-level, regulatory information includes regulatory and submission intelligence / health authority submission / reporting requirements, submission plans for new products and life cycle management activities including regulatory commitments and other obligations, product registration information, labeling, CMC, and safety submissions, communications from health authorities including but not limited to questions and answers during the submission/registration process, submissions (published, both electronic and otherwise), etc. Information can be in the form of data, meta-data, documents and knowledge.

Based on the work done by Steve Gens and Associates (Gens 2018), there are a total of eighteen components being defined as an integral part of the end-to-end RIM landscape of capabilities. Some of these components

represent touch points with other functional processes such as manufacturing change control, supply chain or product release, quality management and clinical for investigational applications.

1. Dossier Management (content plan, distribution, archive)
2. Health Authority Interactions (Q&A, Correspondence)
3. Health Authority Commitments
4. Labeling (core data sheet, eIFU, compliance tracking, artwork)
5. Product Registration Management
6. Regulatory Archive
7. Reporting and Analytics / Integrated Regulatory Information View
8. Submission Forecasting
9. Submission Document Management
10. Submission Production (assemble, publish, QC, dispatch)
11. Design History File – Medical Device
12. Data Management and Information Standards (IDMP, UDI, EUMDR etc.)
13. Regulatory Intelligence
14. Safety Reporting
15. Connection Point: Manufacturing Product Change Control
16. Connection Point: Product Supply Release
17. Connection Point: Clinical
18. Connection Point: Quality Management System (QMS)

While we acknowledge that RIM has broader reach and scope, in this interim consensus paper, we start with addressing some key components of RIM that are traditionally understood as in-scope for RIM. Many topics such as correspondence and commitments, labeling, advertising and promotion, and others are not included in the current version. We welcome broader industry participation and the expertise of individuals who could join our efforts as volunteers to further the cause of this working group and contribute to the creation of artifacts to benefit the industry. As the paper evolves, we will be adding more comprehensive definitions and other components not initially covered by this version of the paper. We expect this to be a “living document” until it covers all the components that are being included within the scope of RIM.

5. Product Registration Management

In general, submission and approval of a marketing authorization application is a prerequisite to launching a product in each country.

Obtaining such approval can be achieved by following different registration paths and regulatory procedures in a specific market, depending on the regulatory requirements in that market. For example, in the European Union (EU), currently there are four different procedures, namely Centralized, Decentralized, Mutual Recognition and National ones for approvals. Some markets may require approval from a major health authority (e.g., US, EU, JP), by requesting a Certificate of Pharmaceutical Product (CPP) to issue approval in that market.

While gaining initial marketing approval may be the first critical step in placing a product in a market, maintaining its life cycle and tracking its registration status, is another equally, if not more, important and challenging activity that the marketing authorization holder (MAH) is tasked with to ensure compliance and keeping the product in the market.

As a common practice, tracking of registrations may start as early as the planning phase for marketing authorization applications, or actual filing, and eventually approvals.

Besides the necessity for permission to sell the product in a market, the registration serves several other purposes, again underscoring the importance of continuous monitoring and tracking of its status. Some of these factors include the following:

- Registrations come with many regulatory obligations and often even with commitments having stringent timelines (e.g., periodic safety update reports, annual reports, label updates, manufacturing updates, risk assessment updates).
- Registration status serves as a basis for regulatory and pharmacovigilance (PV) fees (PDUFA fees in US, PV fees in EU, etc.)
- Registrations require data entry and maintenance of certain product and approval information in regulatory and other databases, within certain timelines mandated by regulatory agencies, such as xEVMPD and SmPC in EU; final approved labels, establishment registrations, Labeler Codes, in SPL Drug Listings in US, and soon IDMP in EU and other ICH regions.
- Registrations also serve as an indicator of what products are approved in each market, which is also a major source of information and driver for Commercial and Supply Chain activities. Furthermore, this information is often requested by health authorities during inspections or via official requests, such as PSMF in EU.
- Maintaining the exclusivity right and awareness of patent expiration for a product in a market is critical and is yet another reason for closely tracking the approval dates.
- It is also important to track the launch date or when the product first becomes available to patients, for commercial and product supply chain and reimbursement reasons.

In some instances, the approval (registration) is temporary or conditional and therefore needs to be renewed after the initial approval period, or once the commitments and requirements are met. Therefore, tracking the approval date is very important to ensure follow-up and maintenance activities are performed and completed on a compliant and timely manner. In some cases, if the product is no longer serving its purpose or has a major safety or quality issue, the MAH may decide to withdraw the registration and pull the product off the market (temporarily or permanently). In other instances, the use of a product may be expanded through approval for use in other indications. In case of mergers and acquisitions, which is commonplace and is a growing trend in this industry, the MAH may transfer the ownership to other entities. Furthermore, co-development, partnership, and working with local distributors, are also instances where the registration information may need updating.

Sponsors working on developing or marketing rare diseases will also be obligated to track the status of their orphan drug designation (approvals) which will help with maintaining exclusivity and other benefits that such designation grants to the sponsor.

Overall, tracking registration status and orphan designations are critical activities for successful business continuity and marketing of products and should be managed meticulously and in a compliant manner, as there are many interconnected activities and dependencies related to keeping a product in a market: change management, label updates, safety variations, supply chain, and M&A among others.

6. Submission Planning

Given the requirements of Registration Tracking described above, it becomes evident that significant effort will be placed in planning the submissions to regulatory agencies, whether they be applications for marketing new products, maintaining the registered status (Annual Reports, Periodic Reports, Renewals, and variations/supplements based on manufacturing and labeling changes), as well as other commitments and obligations.

Submission Planning therefore needs to assist in the management of the anticipated documentation needed for each submission, as well as the resource planning to achieve those submission goals. This should include workflow capabilities that bridge the gap between the tracking of changes in Registration Management and the delivery of those changes to agencies in the form of Publishing & Submissions.

Almost every action taken by a Publishing and Submissions team either inputs or consumes critical RIM data, all while under intense time pressure. For example: from the last complete document to the ability to share that dossier with the health authority is a finite set of time. To ensure quality, validity and accuracy of that dossier, the Regulatory Operations team must go through a series of processes for every document and dataset included in the dossier. Therefore, it is paramount to be able to track KPIs on how long those processes take and optimize them to allow the contributors time to ensure the quality of their deliverables.

This trickle-down and consequence-driven transaction between contributors, operations professionals and global health authorities requires a tremendous amount of coordination. Anyone who's lived through an NDA filing the week before Christmas understands this pressure.

7. Publishing & Submissions

The processes of publishing and submission must be capable of compiling the planned data and documents into the formats required by regulatory agencies. This may be an Electronic Common Technical Document (eCTD), a Non-eCTD Electronic Submission (Nees), or a paper submission divided into volumes and sections. It's advantageous for companies to setup their submission compound document structures as early as possible to avoid being pressed for time to find and link in all the component documents at the end of the process. The publishing process also includes validation of the content and format against agency specifications, which may require integration with validation tools that may be separate from the publishing process because a particular vendor has become the 'best practice' for an agency's submission format. The submission process may also include electronic delivery of the submission content, whether through an agency gateway using an industry

standard such as AS1 or AS2; secure email; or preparing a bill of lading for a common carrier for a paper submission.

The data associated with the volume of a submission can tell a great deal about an organization. Over time, the organization can start to see trends and opportunities within their system as well as ways to streamline the amount of data they provide. When the eCTD was introduced, organizations often included legacy data and items that had been previously submitted to health authorities in different formats (paper). However, as the health authorities come to expect the data in certain formats, with the XML (eXtensible Markup Language) envelope providing the table of contents linking all components, the need to re-send large portions of a dossier has been reduced. A system that tracks the volume of data and information being sent through the system, spotting trends including agency queries, understanding context and flagging redundancy (through new technologies like Natural Language Processing (NLP), Machine Learning and Artificial Intelligence) can start to learn and inform the business process.

8. CMC Submissions

Much of the difficulty attributed to RIM can be attributed to traditional corporate organizations. A hierarchical organizational structure attempts to break critical functions that are necessary to business into separate groups that can specialize on a set of specific tasks, add resources, manage group/department budgets, etc. This structure has been the dominant organization type and yielded enormous benefit throughout modern corporate history, but the advent of technology has made cross-departmental data information flow as much, and perhaps due to the never-ending pressure of competitive markets, more important than whatever benefit is gained by rigidly siloed functional areas. Nowhere is this more evident than in CMC (Chemistry, Manufacturing and Control), where, to name just a few examples:

- Most decisions have a long cascade of impact throughout the rest of the organization, crossing the barriers between R&D and Commercial Manufacturing
- Changes can happen with little or no notice, such as a sudden and unanticipated issue with a supplier or raw material
- Governing regulations proliferate in variety and complexity as the product is sold to more markets, which is also amplified by the number of products carried by a sponsor.

Although accountability for considering and implementing changes lies firmly within the CMC silo, the information about the change is not, at least not to the extent it can impact other line functions such as Regulatory. It is not uncommon for Regulatory to find out about a change that happened five months ago, with the results that depending on the market, the submission may be three months late, due in yet another month, or no submission being required at all.

Who owns what data? If there are a CMC system and a Regulatory system both creating and consuming the same data for different purposes, who owns it? Which organization is accountable? How can the authoritative source be established? At present no system or technology has definitively answered these questions, because at present they are designed for the silo they serve first and make whatever data available to other silos

second. In such situations, it makes sense to establish owners for each business process, data and system to ensure appropriate accountability and governance across functional silos.

9. Data Quality and Data Governance

As regulatory information becomes strategic to the business operations of Life Sciences companies, it becomes important to focus on data quality and data governance as an integral part of regulatory affairs and regulatory operations functions. This can be ensured by defining and adopting Good Regulatory Information Management Principles (Palm-Principe 2017). High-level principles include the following:

1. Treat data or information as a strategic asset
2. Embed data quality across RIM processes
3. Encourage data quality culture
4. Build data quality monitoring and reporting into all processes/systems

Data quality and governance can be enabled in three different ways, which are closely interlinked and perhaps may even seem, overlapping:

People:

- Support end users with entering RIM data right the first time by minimizing entry of duplicate data or free-text data and consistent use of controlled vocabularies or industry standard dictionaries.
- Develop a data quality mindset and culture as part of the training and change management efforts.
- Define data stewards and/or owners for various data elements and train them regarding data quality principles, approaches, tools, etc.
- Define and manage performance objectives around data quality metrics with incentives and/or negative impact.

Process:

- Ensure data entry and management processes are not too onerous, requesting only for information that is relevant to a particular aspect of the process at hand, etc.
- Establish a data governance program leveraging existing data governance methodologies and approaches
- Define processes for data standards management, data quality reviews, data remediation and verification
- Conduct process and information audits.

Technology:

- Eliminate duplicate data entry where possible by integrating with other sources of truth, such as product master data
- Leverage standard reference data dictionaries such as MedDRA, WHO, ISO, etc.

- Improve the overall user experience by enforcing data entry rules, constraints, automatic naming conventions, etc.
- System-driven routines for data quality checks, reports for proactive data quality monitoring, alerts and notifications, etc.

10. Regulatory Intelligence

The US DIA Regulatory Intelligence Working Group defines regulatory intelligence as *“the act of gathering and analyzing publicly available regulatory information. This includes **communicating** the implications of that information, and monitoring the current regulatory environment for opportunities to shape future regulations, guidance, policy, and legislation.”*

We believe that this definition of regulatory intelligence includes both strategic and operational aspects. Strategic aspects include understanding regulatory policies and their implications on regulatory and commercialization strategies. Operational aspects include understanding regulations, guidances, interpretations and industry best practices to implement a regulatory as well as a submission strategy, both for new drug applications and lifecycle management activities. Both the strategic and operational aspects of regulatory intelligence are required throughout the regulatory value chain.

Many companies have defined Regulatory Intelligence, Regulatory Strategy and Regulatory Operations as three separate and distinct organizations, working on different activities across the regulatory value chain. However, traditionally, they have not always been working together. As shown in the figure below (Balasubramanian, 2018), most of the activities across the value chain require regulatory intelligence and understanding of regulatory requirements throughout the regulatory process. This is also true across the R&D and Commercialization value chains. Therefore, we believe the three key functions must work closely together because of the interdependencies shown below. In essence, regulatory intelligence and regulatory requirements form the backbone of the regulatory value chain and therefore must be treated as an integral part of the Regulatory Information Management strategy and capabilities for organizations.



Figure 1. Regulatory Intelligence as Backbone for the Regulatory Value Chain

As part of the RIM Working Group, we will be defining key data elements related to the collection and management of regulatory intelligence and regulatory requirements.

11. Cross Functional Touch Points

When we take a value-centered approach to regulatory information, we see it has a number of cross-functional touch points with other aspects of the product value chain. The figure below shows an illustration with a few examples of the interdependencies on regulatory information – areas such as Clinical, Pharmacovigilance, Supply Chain, Manufacturing, Sales & Marketing, etc. For example, regulatory information is embedded into promotional material, drives clinical development strategy, provides input towards product release, drives safety updates during post-marketing activities, etc.



Figure 2. Cross-functional Touchpoints of Regulatory Information

12. Other RIM Topics

Future iterations of this paper will extend the Regulatory Information Management scope to include topics such as:

- Correspondence and commitments
- Labeling including both the registration as well as artwork management
- Advertising and promotion
- Change control and variation management

13. RIM Elements

As part of the next iteration of this paper and broader mission of the RIM Working Group, we will be working towards defining the higher-level data objects, entities, relationships and data elements along with their defining characteristics or attributes which will then be shared with the broader RIM community for review and feedback.

14. Conclusion

As the RIMWG continues to evolve, and the discussion begins to crystallize around a truly beneficial industry consensus on what we mean when we say RIM, or RIM systems, we plan on publishing a sequel to this paper that will provide the details gleaned from the conversations and agreements that the RIMWG produces. We imagine there may be the need for even more iterations of this paper, as the topic of RIM is evolving, exemplified in debates such as what data from a Change Control process and system constitutes Regulatory Information, or what information does Regulatory own, as has been seen in the case of the preparation for the IDMP implementation in Europe.

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