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Specific considerations for RIMS upgrades as data-driven submissions ambitions grow

Considerations and emerging leading practices as Life Sciences organizations look to comply with the latest regulatory requirements **and** drive new operational efficiency and greater strategic intelligence

Summary

Although the regulators are providing guidance around the data submission requirements in an iterative manner, companies should consider getting their RIM system configurations upgraded, existing data remediated, processes optimized and data quality and governance functions in place now, instead of awaiting final requirements to be shared by the health authorities.

Even though every life science company might be at a different stage of their RIM upgrade implementation, it is required to consider a systematic manner of making this change across the organization by keeping in mind the multiple challenges which they can face across their subfunctions in not just making the change but also adapting it.
Specifically, remediation of existing data within RIM and ensuring defining the correct quality standards based on regulatory requirements and processes to capture the required data is the need of the hour. Further establishing an enterprise-wide data governance function (if not already) linked to the Regulatory function to allow for defining a set of data owners/stewards who cannot just help align the RIM data with regulatory requirements but also maintain it. Part of the challenge around data governance within RIM is that regulatory doesn't own much of the RIMS data and Data owners can reside outside of the Reg function which needs to be evaluated by the organizations to ensure the right standards are being defined and applied as a part of the system upgrade.

Keeping in mind that the end goals are, or ought to be, much more than compliance with a single set of defined regulatory requirements (such as EU IDMP) should help keep initiatives broad, all-inclusive and continuously evolving, while ensuring that the company itself gains the maximum returns - from:

- Enhanced data quality;
- Tighter integration of definitive, high-quality product data with business processes and reporting;
- Optimized/accelerated health authority interactions;
- Richer regulatory intelligence; and
- Reduced operational complexity through closer integration between business functions.

Introduction

Life Sciences industry regulators have become increasingly focused on data-driven submission processes as a means of managing marketing authorization submissions. A raft of new and updated standards has created new impetus for drug and device companies to tighten up and broaden their regulatory information management across the product development lifecycle as a matter of strategic importance.

Potential associated benefits to companies themselves, of embracing enhanced process and data quality rigor is a cornerstone to support data-driven processes, include improved trust in data to suggest essential decision-making; tighter integration of core data with business processes and reporting; optimized/accelerated health authority interactions; increased regulatory intelligence; and streamlined data exchange between business functions.

Effective initiatives will involve a rethink not only of current system capabilities, but also of the processes involved in capturing, managing and using the richer data reserves that companies should consider now building. The more that original data (rather than compiled documents) becomes the foundation for submissions and associated regulatory exchanges, and to inform internal decisions, the more robust and reliable the quality, and completeness of that data needs to be. This means regulatory information management system (RIMS) upgrades should be approached holistically, and not just as a technology-specific project.

This paper sets out some of the associated challenges that can emerge as companies tackle their RIM solution upgrades and provides targeted recommendations for getting ahead and effectively realizing the fuller business benefits of a well-rounded, data-driven RIM capability.

Common issues can be broken down into system challenges, process challenges, and matters of data governance, as discussed on the following pages.

System Challenges

Although the transition from document-centric information delivery and management to a data-first environment is not entirely a technology issue, technology will form the foundation through which everyday order, consistent format and structure, data quality, and status visibility are maintained and improved.

Many companies have realized now that there may never be a definitive point in time when all the new requirements are set in stone, because Life Sciences as an industry is evolving continuously.

A more agile methodology should be sought to facilitate ongoing flexibility.

But this can bring its own challenges as teams adapt to the new way of working:

1. The need to develop an agile mindset around the RIMS upgrade

Regulators themselves are embracing an agile approach to development and implementation of new requirements and ways for the industry to interact with their systems (e.g., SPOR, PLM portal in the EU), which is reflected in the iterative rollout of IDMP guidance and target submission requirements.
This drives home the understanding that the fuller upgrade requirements are unlikely to be defined and known before a RIMS upgrade gets underway, meaning that the finer details will need to be addressed via new rounds of discussions with the different business stakeholders.
Adopting this mindset of refining requirements in next iterations can be difficult to adapt as companies have been used to implementations with fixed/pre-known parameters.

System Challenges

2. Gaps in existing data captured within the central RIMS

Up to now, companies have had the flexibility to define the data and processes based on their own requirements. Yet, because the implementation of these processes to enter data was not geared toward data-driven submissions and related regulatory requirements, there are likely to be gaps in the data that currently exists in the RIMS.
New regulations are likely to require submission of some mandatory fields or use of Health Authority-defined controlled vocabularies, which up to now may exist only as optional and non-standardized fields within the current system. Technology teams will need to work with the relevant business stakeholders to work out how best to address those gaps so that they correctly fulfil the emerging requirements

3. Data collection efforts required for upcoming regulations

In addition to getting existing data in order, technology and functional teams will need to establish new/additional data fields that must now be populated, under EU IDMP for instance. This has implications not just for the upagrade of the RIM system, but also for the collection and entry of the data within the applicable data model field/object, with appropriate links to existing records. For instance, new values around excipient and device information will need to be collected and stored within the RIM system now. Addressing these gaps across multiple products can demand significant effort.

System Challenges

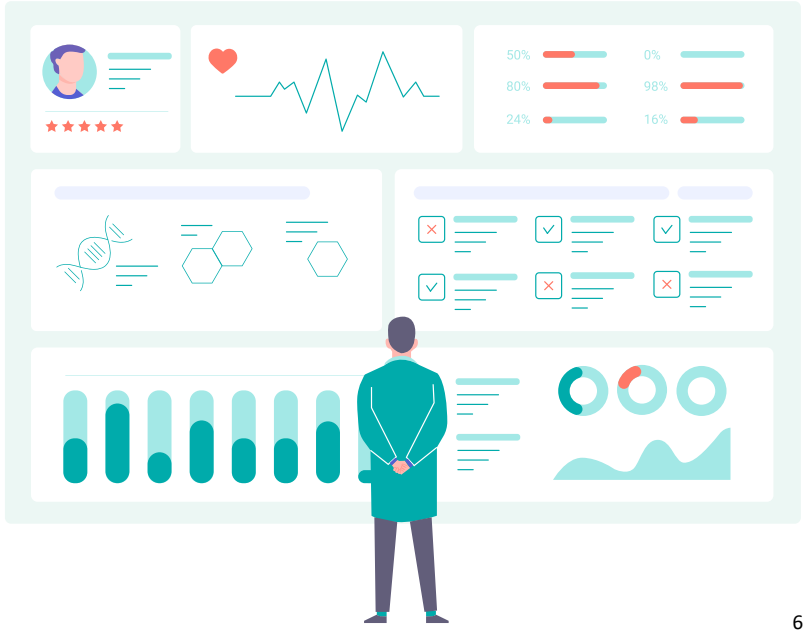
4. The need to transform existing data to the new standard fields as the data model is updated

Whatever work the major software vendors may be doing to align their RIM platforms or solutions with the evolving new requirements of the main regulators, this on its own does not make existing data compliant within the updated RIM system. Rather, existing data may need to be transformed to the new standard fields as the data model is updated, which is not a simple undertaking. Provision needs to be made so that, from now on, data/records are stored and linked in the desired manner.

Although software vendors may provide out of the box tools to support data loading and transformation efforts (e.g., Veeva provides data loader sheets), using these out of the box tools will not automatically deliver the data transformation. Appropriate knowledge and preparatory work is essential so that in the future all data in the updated RIMS system can be relied upon as correct and compliant.

5. Establishing and embedding the culture and approach around data quality management

To ensure that the data referred to in future for all aspects of regulatory exchanges, operational checks, and strategic decision-making is correct, reliable, and compliant, companies should establish formal parameters for reviewing all of this. These include validation rules within the RIMS, and the implementation of frequent data quality audits, with KPIs and appropriate reporting - both today and in the future.



System Challenges

6. Existing reports will need to be assessed based on the system upgrade

Since the existing fields might get modified due to the RIMS upgrade, the current reports used by business users may likely need to be assessed to determine no impact to business continuity. Working with the business, technology teams should identify which reports will be affected by the system upgrade and which of these are business critical. Review of existing report specifications should be treated as part of the upgrade project to facilitate business continuity post go-live.

7. Existing systems integrations will need to be reviewed

Any existing system integrations will need to be assessed based on the RIM system upgrade, for the potential impact on upstream/downstream systems interacting with the RIM system. The upgrade might mean that existing data is not available in the same location going forward or be at a different level of granularity, so an assessment and advanced precautions will need to be taken to ensure that upgrade doesn't impact business continuity.

System Challenges

8. Decisions will be required about legacy data/product information management

When it comes to populating upgraded RIMS, the teams involved will need to make decisions about where to draw the line with the data being transformed and managed on an ongoing basis, which will require discussion. If there are older product lines that have long been discontinued or superseded (e.g., inactive registrations), it may not be worth transforming and preparing associated data for use in the enhanced, newly configured, live RIM platform. Archiving may suffice, unless there is a specific use case for actively managing the associated product information in conformance with the latest data formats.

Process Challenges

While updated technology provides the backbone for data-based regulatory submissions and smarter operations management, the scope for effective transformation will be severely limited unless associated business processes are optimized to take advantage of the investments in a particularized and continuous flow of good-quality, standardized product and registration data. This starts with ensuring that the updated system will actually work better for everyone.

1. Integration of business & system processes

Recent years have seen an increase in the interface between end-to-end regulatory business processes and RIMS. With increased dependence on and requirements for regulated data, RIMS is finally gaining traction as the lynchpin and, crucially, the facilitator and enabler of the regulatory function.

While, ideally, the updated system will be modeled based on the needs of specific business processes, in reality business processes are likely to need to be (re-)modeled to work efficiently with the functionality of RIMS wherever possible. System customization, which should be avoided ideally, risks pushing up complexity and cost in an environment that standardization is looking to simplify and streamline. The good news is that preferred reporting, workflow, and new forms of data capture are likely to be supported by the upgraded capabilities, negating any customization.

To reduce the potential burden on process documentation redesign, system processes should be separated from business processes, with a clear indication of interfaces with system processes in the business process documentation (e.g., as part of submission process, documentation of submission timelines should happen in the RIMS as these timelines are being identified. The actual data fields, system workflows, etc., should be described in a separate document).

Setting up a process framework using a (Business) Process Architecture methodology can alleviate some of the challenges encountered. This framework can be utilized to create the big-picture end-to-end process (i.e., allowing a clear overview of all of the process steps), increasing everyone's understanding of relationships and dependencies between specific processes, while also making it possible to capture and drill down into more detailed process steps as needed.

Process Challenges

2. Change in system functionality.

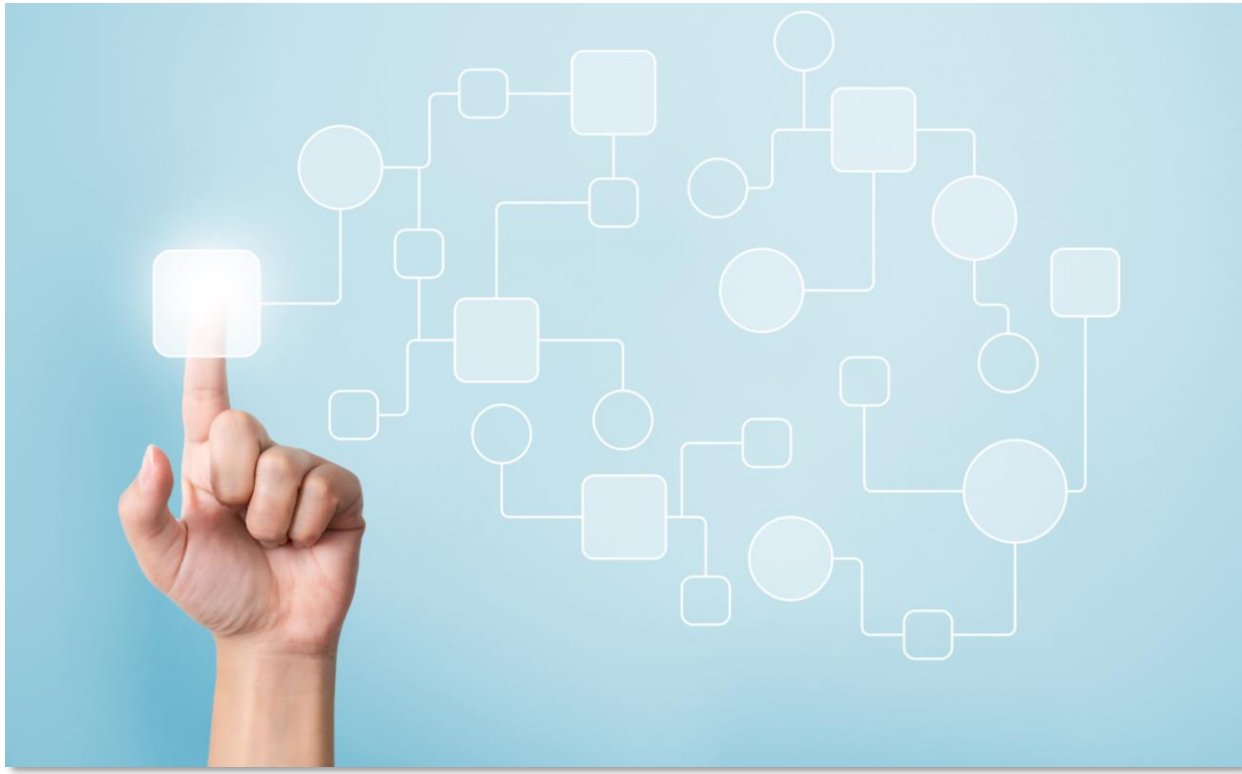
It is unavoidable that the addition of new data-based capabilities, for instance in preparation for EU IDMP compliance, will require the adaptation of business and system processes. Companies tend to capture this kind of thing in their own way, through numerous updates and changes to documentation. This can be a laborious and inefficient process if done manually, often involving a lot of duplication. There may be an over-reliance on including screenshots, for instance; multiple documents may mention the same system objects/entities; and/or there may be separate but overlapping documents discussing 'how to operate the system' versus 'how to carry out business process A in the system'.
Considerable duplication of documentation can exist across functional subdivisions, too, e.g., 'labeling variation' document vs 'CMC variation' documents.
Harmonizing these documents so that there is one master that includes the different scenarios broken down, can substantially reduce the documentation and update effort – and the associated user training.

Data Governance Challenges

The efficacy of transformed RIMS capabilities and updated processes relies on one further yet essential dimension, which is the quality and integrity of the underlying data and how well this is upheld and improved over time. This requires systematic data governance.

Life Sciences companies are still struggling with setting up proper data governance measures today. Unless these are addressed, those organizations risk compromising the potential of their RIMS and process optimization.

Although there has been a rise in enterprise-wide initiatives being considered, fully-realized data governance implementations are lacking at this point. This is largely due to the enormous scope of enterprise-wide data governance projects which can take several years to yield first results. For this reason, while RIMS-oriented data governance has become a focal point at many companies, the measures being planned and rolled out are not mature yet - due to the different dimensions and apparent complexity that are involved in getting this correct.



Data Governance Challenges

From a RIMS upgrade/implementation perspective, data governance involves the following specific and interrelated challenges:

1. Data roles (including data owner, data stewards) to date are not as clearly defined as they need to be, given the increase in system capabilities and data scope. By now, a governing body and associated process should be in place to allow for assignment of data related roles and responsibilities and managed for RIM and coordinated across functions.

2. Data definitions, business rules, and data quality requirements and metrics will need to be established too now, due to the increased scope of the data and managed processes. A unit dedicated to this can help ensure this is achieved in a timely fashion, taking into account both the system specifics as well as the overarching regulatory and business requirements.

3. With the increased importance of EMA's SPOR data management services, having central coordination of controlled vocabularies, organization records, substance information, and specific product identifiers in near future will be an essential capability whether at the application /function level or cross functional.

Focusing data governance efforts around a RIM implementation/upgrade program and associated data can be much more effective in the short term, as a targeted initiative that will ultimately contribute to that wider enterprise ambition. Without this overarching structure, it will typically be a lot more cumbersome to access the required knowledge, to secure agreement on definitions, and so on.

Considerations

With so many considerations, and so much at stake, Life Sciences organizations can become 'stuck' in knowing how best to proceed, especially when they want to achieve key milestones within an acceptable timeframe and deliver tangible ROI in an agile manner.

Based on our extensive client work to date, we have distilled the following roadmap of actions, and can provide targeted guidance at any or all stages of this pathway.

1. Multiple business stakeholders/subject-matter experts need to be involved and have a detailed understanding of the intended data model, as well as the target system and business processes. Ideally this knowledge should be shared between multiple subject experts - to mitigate the risks of burdening one person; or a specific individual not being available.

2. Accepting that evolving data governance practice is a requirement for many Life Sciences companies now, processes and structure will need to be refined to ensure ongoing control and governance around collected and remediated data, and for BAU processes to capture data correctly and maintain the quality. Effective data governance is a pre-requisite for RIM system upgrade, along with process considerations as part of existing Quality work, so establishing a data governance body with defined roles and remits should be a priority from early on.

3. Business reporting, using data in the RIM system (both for regulatory compliance and process checks/efficiency), should be considered and provided for in its own right - by region, by timeline, and so on. It will be important to review the impact of the RIM system upgrade on both current and planned reports, as well as the scope for new reports that could be established with the new capabilities and RIM data enhancements.

4. As a part of the system upgrade/implementation, existing data within the RIMS should be remediated proactively to ensure it is reliable, that it complies with upcoming regulations, and that it can be trusted as a definitive source of truth to empower smarter decision-making, while reducing repetitive data re-entry.

5. Finally, there needs to be clear and proactive communication about regulatory expectations to end users and leadership, given that this is effectively a change management program. This also requires appropriate training, bringing everyone up to speed about the new enhanced role of data, and a building of awareness and appreciation of everyone's respective responsibilities in upholding the integrity and value of product data wherever it is captured and wherever it appears/is used. Specific omeasures may include:
    - Informing teams about clear change management activities as part of the project, to ensure widespread awareness of this and of the related processes, once the new RIM and data-based processes are live.
    - Ensuring an appropriate level of (re-)training for all affected stakeholders.

Taking action

To learn how Deloitte can help your organization update its RIM capabilities and refine and streamline the use of product data across the enterprise, please reach out to us.

About the authors

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