1 A General Framework for Regulatory Intelligence in Medical Product Research and Development

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Introduction

Over the last 30 years, regulatory intelligence (RI) has grown from a new concept to a key component of regulatory affairs. As more information became publicly available and regulatory science advanced, using data and insights from the regulatory landscape has become standard in business decisions. This is especially important for regulatory affairs professionals working on the research and development of drugs, biologics, medical devices, and digital health technologies. RI programs aim to support the timely, informed decisions needed to deliver safe and effective medical products to patients.

Even though RI is now a core skill, the types of activities and roles involved can vary significantly from one company or person to another. At the RAPS (Regulatory Affairs Professionals Society) Regulatory Intelligence Conference[1] held in Baltimore, Maryland, in March 2025, this variety was clear in both the topics discussed and the backgrounds of attendees. Some attendees came from regulatory policy perspectives with backgrounds in trade associations and agency surveillance. Others came from a regulatory strategy perspective with backgrounds in product development and interfacing with regulatory agencies on clinical development programs and labeling negotiations. Still others came from backgrounds in quality assurance, pharmacovigilance, change management, good practices compliance, and audit preparation. While everyone uses public information from agencies like the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA), they often use it in different ways and may not always agree on what RI means. These differences can make it harder to work together on RI projects or see the whole RI picture across an organization **(Figure 1-1).**

Looking back on the conference and the range of perspectives in the RI community, it is clear that a unified, general framework is needed for all RI activities in medical product research and development. The General Framework for Regulatory Intelligence in Medical Product Research and Development (R&D) introduced in this chapter aims to provide a shared language for discussing RI concepts and a way to assess your team's or vendor's RI capabilities. Most importantly, this framework is designed to be flexible and adaptable to your needs. Feel free to discuss, challenge, and adjust it to fit your organization.

Background

RI is not a department or job title. While some teams and professionals have "regulatory intelligence" in their titles, many people perform RI work without it being explicitly mentioned in their roles. Before outlining a framework, let us examine some regulatory affairs roles in medical product organizations that often involve RI activities, even if not explicitly labeled as such. The exact roles and responsibilities may differ in your organization, but these examples show the range of teams involved in RI.

Figure 1-1. Different Perspectives on Regulatory Intelligence

Regulatory Strategy

Regulatory strategy teams help expedite the approval process for medicines by ensuring that development plans adhere to regulations and meet the expectations of global health authorities. They build clear road maps for how and when to file, how to work with agencies, and how to manage risks around approval and labeling. They constantly track what regulators are approving, what new guidance is being released, and what changes are being made to submission requirements. They share this intelligence with their teams, adjust plans as needed, and keep everything aligned with the latest regulatory thinking.

Regulatory Labeling

Regulatory labeling teams make sure that product information is clear, accurate, and meets the needs of patients, physicians, and regulators. They create and update key documents, such as package inserts and instructions for use. They ensure that everything aligns with the product's goals and regulatory standards. To stay on track, they keep an eye on what regulators are approving and any new labeling rules or guidance. Cultural contexts and the changing needs of patients must also be monitored and incorporated. They share this intelligence with their teams and adjust documents as necessary to ensure compliance and alignment.

Advertising and Promotion

Advertising and promotion (ad/promo) teams ensure that promotional materials are clear, truthful, and comply with the rules, enabling products to be marketed confidently and responsibly. They review and approve content, help shape claims, submit materials to regulators, and train teams on how to communicate in a compliant way. To stay current, they track new guidance and trends from health authorities. They share updates with their teams and adjust materials as needed to stay aligned with the latest standards.

Regulatory Operations

Regulatory operations (reg ops) teams ensure that submissions to health authorities are complete, correctly formatted, and submitted on time. They build and manage submission packages, keep filing plans up to date, and handle electronic systems and records. To stay current, they track changes in submission rules and templates, share updates with their teams, and adjust their work to meet the latest requirements.

Regulatory Policy

A regulatory policy function ensures that the organization is prepared for and can influence evolving regulatory landscapes. Policy professionals develop position papers and internal guidance, as well as create and execute engagement strategies to help the organization respond to external changes and shape policy. These external engagement strategies can include public commenting efforts, attending agency public meetings and workshops, and participating in trade and professional organizations. To fulfill these responsibilities, policy teams continuously monitor health authority announcements, share relevant information with their stakeholders, evaluate the impact of agency changes on their deliverables, and take actions based on their evaluations and engagement strategies.

Regulatory Safety and Pharmacovigilance

A regulatory safety function collects and reports adverse events to health authorities, prepares safety summaries, manages risk plans, and updates product labeling based on new safety data. To fulfill these responsibilities, safety teams continuously monitor the external environment for safety signals from a broad range of sources, including agency websites and databases, product labels, social media, among many others. In addition, they monitor agencies for changes in safety reporting guidelines, templates, and requirements. This information is then shared with their stakeholders, evaluated for impact on their reporting obligations and processes, and they take the appropriate action based on their evaluations and reporting plans.

Regulatory Chemistry, Manufacturing, and Controls

A regulatory chemistry, manufacturing, and controls (CMC) function ensures that the manufacturing and quality aspects of a product meet regulatory standards throughout its lifecycle – from development through commercialization. Regulatory CMC professionals prepare the manufacturing and quality sections of regulatory submissions, manage changes to production processes, support global approvals and compliance, and participate in trade associations and standards organizations. To fulfill these responsibilities, they monitor health authorities and standards organizations for changes in requirements, communicate new requirements to their stakeholders, and take the appropriate action to create and maintain their deliverables.

GxP Quality Assurance, Compliance, and Audit

These functions are essential for ensuring their organization's good manufacturing, clinical, and laboratory practices (GxP) are effective and compliant. Quality assurance (QA) professionals manage quality systems, conduct audits, support regulatory inspections, and oversee training, deviations, and corrective actions. To fulfill these responsibilities, QA teams monitor health agencies for changes in standards and guidelines, enforcement action publications, and other information that may impact their role. They communicate new information to their stakeholders, evaluate the impact of new requirements and precedents on their deliverables, and take the appropriate actions based on their evaluations and plans.

These diverse functions highlight the multifaceted nature of regulatory affairs, as well as how RI is distributed across organizations. By understanding the variety of responsibilities and activities, we can better appreciate the common threads that form the foundation of RI. This context sets the stage for defining a generalized framework that captures these shared

capabilities, providing a cohesive structure for RI that can be applied across various regulatory affairs functions.

General Framework for RI

Although the detail of their work varies, these regulatory affairs functions exhibit four common features that serve as the basis of RI capabilities **(Figure 1-2)**.

- **Observe –** Someone observes a change or event in the regulatory landscape. This event could be a new product approval by an agency, the release of new guidance documents, an agency enforcement action, or some other activity by a regulatory agency. The observation could come from a formalized continuous monitoring program or just one motivated individual who recognizes the value of paying attention to the regulatory landscape.
- **Communicate –** When interesting or relevant events are observed, the observer communicates them to a broader group of stakeholders. Communication can take various forms, including email, newsletters, meetings, presentations, or other means. Knowing how and when your stakeholders want to receive the information is a key element of successful communication. In some organizations, this communication may also involve an observer capturing the event in a personal notebook or tracker for future follow-up.
- **Evaluate –** Stakeholders then evaluate the event for potential impact on the team's product strategies, quality systems, reporting obligations, compliance programs, or other aspects of the organization. Through this evaluation, they glean data and develop actionable insights that apply to their role, to the patients they serve, the products they're developing, or other parts of their organization.
- **Act –** Lastly, the stakeholders take some action based on the data and insights gleaned from their evaluation. These actions could include updating product-specific strategies, deciding on regional expansion plans, requesting and conducting meetings with health authorities, revising specific policies and procedures for compliance programs, or a variety of other actions. It is this last component, action, that is the key distinguishing feature of truly robust RI programs. RI programs are not designed to merely disseminate information and generate speculative analysis or compliance checklists. They must drive intelligent actions and decisions that enable the delivery of safe and effective medical products to patients.

In summary, RI is the set of capabilities enabling medical product R&D teams to inform their strategic decisions and actions with data and insights gleaned from surveilling the regulatory landscape. This general framework for RI serves as a cohesive structure that integrates the RI activities of various regulatory affairs functions into four core capabilities: observe, communicate, evaluate, and act.

To further understand how these four components work in practice, let us unpack the combination of people, processes, and technologies within each of the four components.

People Roles and Organization

The roles and organizational structure of each RI program depend heavily on the number and experience of people involved. In some small organizations, for example, all four components of an RI program are performed by one or two individuals who may or may not have RI in their titles **(Figure 1-3)**. At the RAPS Regulatory Intelligence Conference, I met several heads of regulatory and quality from small medical device and drug companies who perform every aspect of RI themselves. They monitor regulatory agencies and communicate updates to senior leadership, evaluate changes for their impact on product development and quality systems, and execute projects for global marketing authorizations and product quality campaigns.

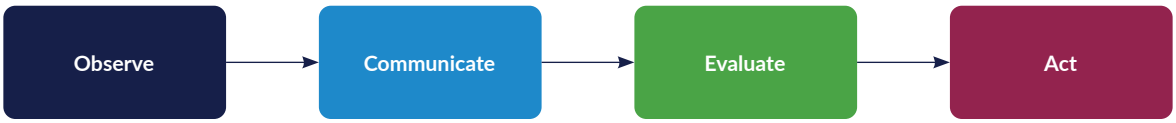
On the other end of the spectrum, some large organizations have dedicated teams specializing in discipline-specific RI activities for labeling, regulatory strategy, regulatory policy, regulatory CMC, regulatory pharmacovigilance, and so on **(Figure 1-4)**. In these organizations, no single individual performs every RI activity; they are shared across a wide range of participants across multiple teams.

These two examples are bookends on a spectrum, and most organizations fit somewhere in between them.

In addition to roles and responsibilities, each organization's capacity to leverage RI depends on the skills and experience of its people. Like any other skill, RI requires intentional practice and training to develop. Even if no one in the organization has RI in their title, training programs and learning opportunities should be provided in the areas of locating public and internal sources of regulatory information and precedent, conducting data-driven precedent research projects, detecting and analyzing trends, performing impact assessments to develop insights and action plans, and using regulatory insights to develop product- and program-specific strategies.

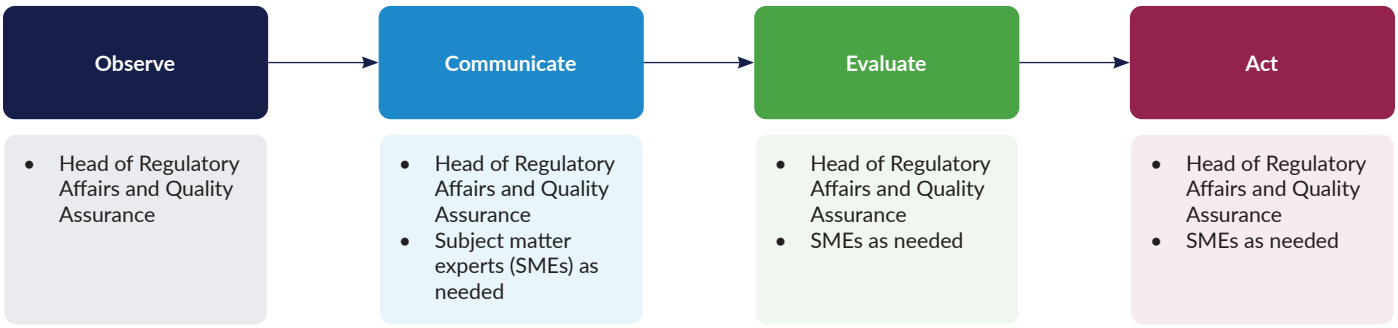
Training can be developed and delivered by in-house subject matter experts or consultants. Professional

Figure 1-2. Common Components of Highly Effective RI Programs



Source: Chris Whalley

Figure 1-3. RI Roles in a Small Organization



Source: Chris Whalley

organizations such as RAPS,[2] DIA,[3] and the Organisation for Professionals in Regulatory Affairs (TOPRA)[4] also offer sessions and workshops specifically on RI skills.

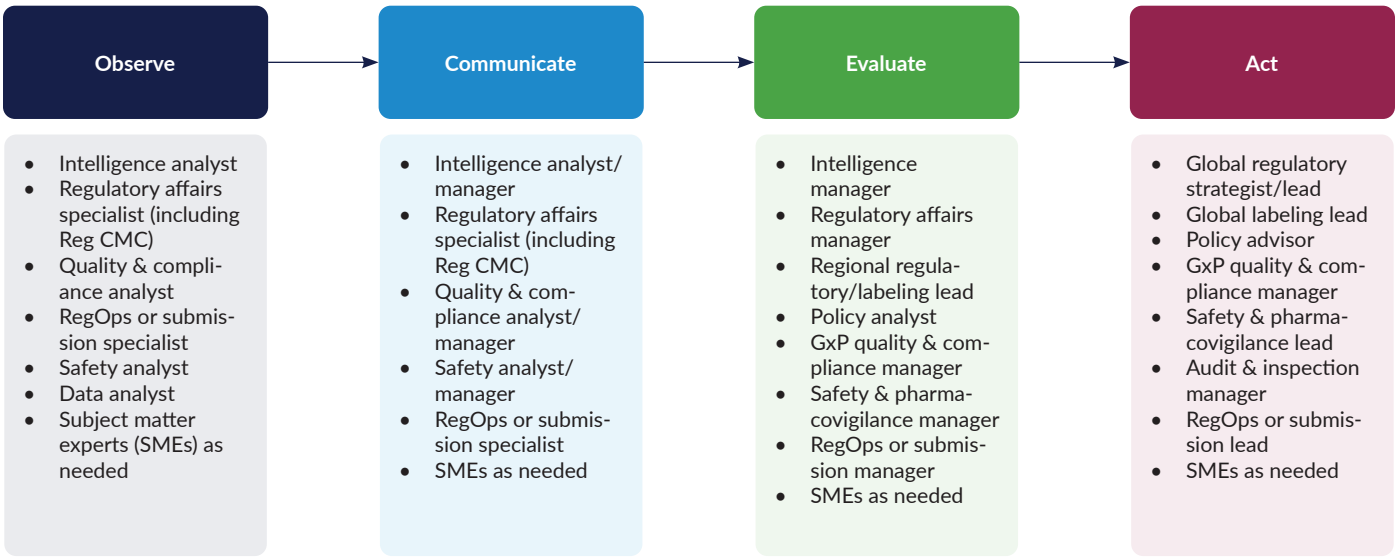
RI Processes

Focusing on processes has benefits and drawbacks. Processes can help ensure consistency, quality control, and make it easier to train and onboard new colleagues. However, too much focus on process can slow down innovation, make it hard to adapt to regulatory changes, and lower morale if employees feel restricted by strict rules. With this in mind, the processes described here are meant to guide, not dictate, how you approach RI.

Moving from left to right across the four RI components of the framework, raw data and information are collected from sources and transformed into insights that drive intelligent actions within the organization **(Figure 1-5)**. Although each organization may organize its processes around its unique needs, there are some core RI processes that we'll unpack here.

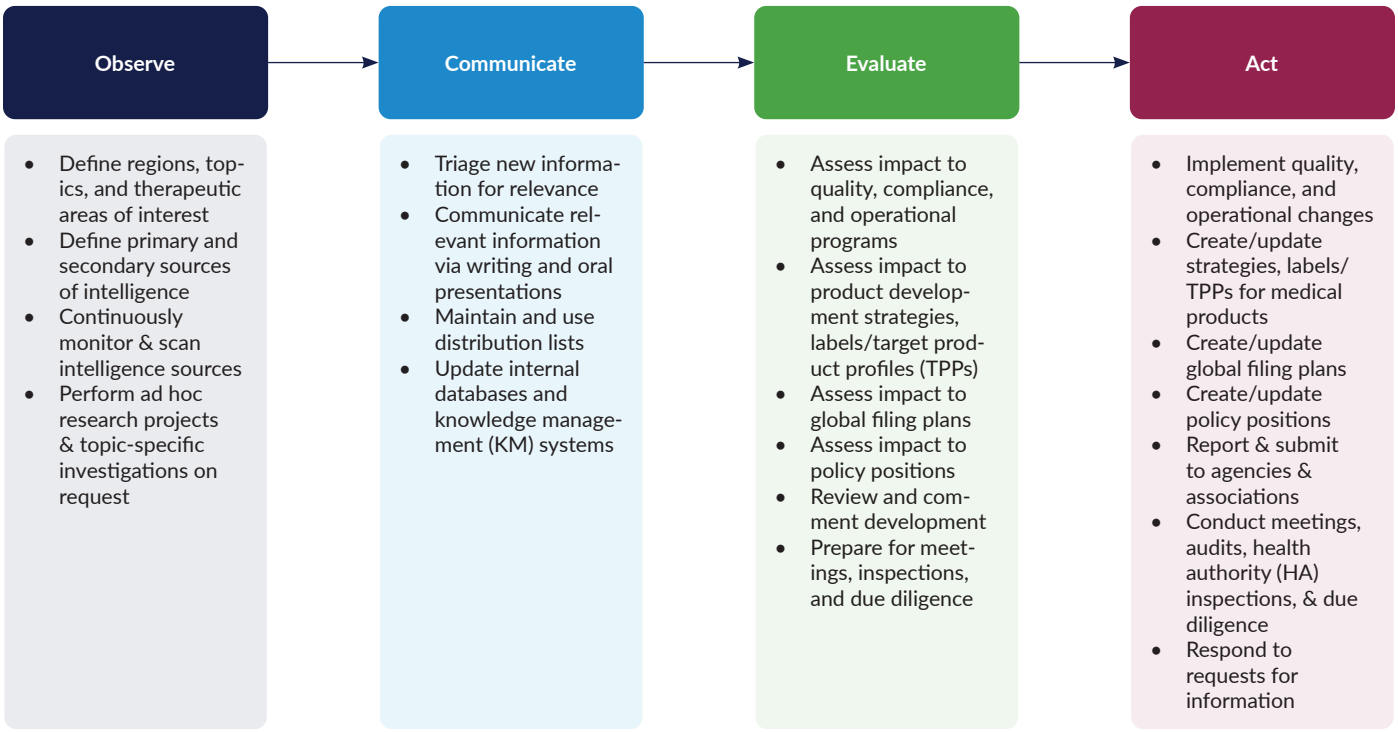
Observation Processes. Defining the regions, topics, and therapeutic areas of interest to your organization is crucial for tailoring research and development efforts to specific needs and opportunities. The selection of regions, topics, and therapeutic areas is driven by numerous factors specific to each organization, including the types of products, stage of development, commercialization plans, leadership interests, and other factors. The key is that each organization needs to identify where and what its RI program should focus on. These areas of focus should be periodically reevaluated to ensure the RI program consistently meets your current business needs.

Figure 1-4. RI Roles in a Large Organization



Source: Chris Whalley

Figure 1-5. Processes Within Each Component of an RI Program



Source: Chris Whalley

For each agency or organization you are following, here are some examples of the types of information RI programs can involve:

- Agency regulations and policies;
- Guidance for industry;
- Regional and international standards;
- Product approvals, safety changes, and assessment reports;
- Meeting announcements; and
- Publications by agency authors (interviews, conference presentations, journal publications, etc.)

Once the areas of interest are defined, establishing primary and secondary sources of intelligence is essential for gathering comprehensive and reliable information. Primary sources, such as agency websites, public meetings and workshops, agency-authored publications, and internal team experiences, provide firsthand insights and data. Secondary sources, including media reports, commercial database providers, trade associations, and consortia reports, among others, offer valuable context and background information. For most organizations, it is unlikely that a single source of information will provide all the information you need. By leveraging multiple sources, organizations can build a robust foundation for their RI program.

Once primary and secondary sources of information are established, continuously monitoring and scanning them is vital for staying current with the latest developments and trends. This proactive approach involves regularly reviewing new and revised information to ensure accuracy and consistency. The frequency and depth of monitoring will depend on the size and skills of your team, as well as the technology used. By continuously monitoring your sources, organizations can quickly identify emerging opportunities, potential threats, and shifts in the regulatory landscape, enabling them to respond swiftly and effectively.

In addition to continuous monitoring, project-based research is also required. These "ad hoc queries" can happen any time and may occur in response to management questions, requests for information for health authorities, preparation for meetings and inspections, or other factors. Performing ad hoc research projects and topic-specific investigations on request allows regulatory teams to address specific questions using the sources of information to which they have access.

Communication Processes. As you continually observe the regulatory landscape, you will receive numerous alerts, only some of which will apply to your organization. Establishing an efficient triaging process to review and filter this incoming information is crucial. By quickly sorting relevant information from irrelevant information, you allow your team to focus on the most impactful updates, reducing information overload and enhancing the overall efficiency of your RI program. The triaging process your team follows will be specific to the people and tools you employ.

As you detect new relevant information, you need to communicate it to your stakeholders. These communications

can take many forms, and you should establish a structured approach to disseminating your RI alerts. These updates could be written via email or newsletters, provided verbally during team meetings, or taken through other approaches. For teams with digital knowledge bases and databases, updating these systems can be a vital way to communicate intelligence signals to colleagues. Regularly refreshing these systems with the latest information ensures that your stakeholders have access to current and reliable data.

When communicating updates from your continuous monitoring program, you will typically need to summarize them by highlighting the following information: a description of the news item, a summary of any changes from previous version(s), and an assessment of the potential impact to the organization. The level of impact assessment will vary depending on the structure of your team and their responsibilities.

For request-driven updates (sometimes called ad hoc requests), the content and format of communication should meet the needs of the person or team requesting the information. If they need to present the findings in a meeting, then slides may be appropriate. In other cases, an email or narrative document may be better. If the findings are the result of data analysis, then the raw data and explanation of the data analysis methodologies should also be included in the communication.

Part of communicating the alerts is knowing who needs to receive information based on the topics and areas of interest. It is not a trivial task to keep track of distribution lists for your team, and part of establishing a structured approach to disseminating information should include maintaining and using RI distribution lists. Wherever possible, you should provide stakeholders with mechanisms to manage their own subscriptions to these lists, rather than trying to manually maintain the lists yourself. Allowing stakeholders to manage their own subscriptions fosters personal responsibility for RI engagement, ensures lists are updated based on stakeholders' current role, and allows RI staff to focus on strategic activities rather than administrative processes.

Evaluation Processes. Evaluation is where information transforms into insights. Each regulatory affairs function evaluates new information through the lens of its own responsibilities. However, the underlying principles remain the same: assess what has changed, determine its meaning in terms of impact (or potential impact), and decide what, if any, action is required. This shared structure promotes consistency and quality in decision making while allowing for discipline-specific interpretation.

For regulatory strategy teams, evaluation tends to focus on how new guidance, precedent, or agency actions may influence product development plans or agency interactions. A newly issued EMA guidance document on decentralized trials, for example, may prompt a structured review of how ongoing clinical protocols align with the new expectations. Teams assess the relevance to each development program, the feasibility of adapting new practices, and the potential for benefits or risks to regulatory strategies.

In regulatory labeling, evaluations may concentrate on the impact of new labeling standards, precedent, safety information, or class-wide changes. A team can compare a new FDA safety labeling guideline with their product's current label or target product profile (TPP), identifying discrepancies and preparing recommendations for updates. Evaluations here emphasize clarity, compliance, and consistency with emerging patterns.

For regulatory CMC functions, evaluations may center on how changes to manufacturing standards or quality expectations could affect ongoing or planned submissions. When the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[5] revises a Q-series guideline,[6] for example, CMC teams typically conduct a gap assessment against internal procedures to determine whether any control strategies, specifications, or validation data packages require updates.

Regulatory policy and pharmacovigilance teams conduct broader, often cross-functional evaluations. Policy specialists may analyze a new agency framework for digital health technologies, synthesizing insights from subject matter experts to inform an organization's position or public comments. Pharmacovigilance professionals may assess new signal detection requirements to determine whether internal safety monitoring systems are still compliant.

In all cases, effective evaluation depends on traceability. You should document how information was interpreted, who was consulted, and what conclusions were reached. This recordkeeping supports transparency, accountability, and reuse of insights in future projects. Maintaining a structured, flexible, and repeatable approach to RI evaluations enables organizations to respond quickly to the evolving regulatory environment.

Action Processes. Action is the defining characteristic of effective RI programs. Without it, intelligence remains theoretical and disconnected from the organization's goals. The types of actions taken depend on the regulatory affairs team performing them. However, all are aimed at improving decision quality, compliance, and ultimately, patient outcomes.

After completing evaluations, teams may implement operational or quality system changes. For example, a GxP quality group may update standard operating procedures following the evaluation of new agency inspection trends. These updates would ensure that the organization's good practices align with the latest expectations and minimize the risks of inspection findings.

Product-focused teams often revise strategies, labels, target product labeling (TPL), or TPPs based on regulatory insights developed from the evaluation of new precedents and product-related actions taken by health authorities. A regulatory strategy team might modify a clinical development plan to include an additional end point highlighted in a recent approval. In contrast, a labeling team may incorporate updates to contraindications or harmonized terminology as a result of RI programs.

Other actions involve policy and advocacy activities. When new guidance or draft legislation appears, policy teams

may coordinate internal reviews, draft company responses, or collaborate with trade associations to influence the external environment. When agencies announce new public workshops and meetings, advocacy teams can use this information to plan their attendance and prepare any talking points they wish to discuss in advance. These actions demonstrate how RI supports proactive engagement with regulators rather than passive compliance.

Reporting and submissions are another common form of action. RI findings can trigger the preparation of safety reports, supplemental filings, or agency briefing documents. Similarly, meetings, audits, and inspections rely heavily on intelligence gathered and evaluated in advance. Teams use RI outputs to prepare evidence packages, respond to agency requests for information, and plan corrective or preventive actions.

Finally, RI can also drive due diligence and business decisions. When evaluating a potential partner, acquisition, or in-licensing opportunity, RI insights about the target's regulatory status, inspection history, or policy risks can shape negotiation strategy and valuation.

In mature RI programs, actions are tracked and fed back into the observation cycle. This feedback loop closes the intelligence process, creating a flywheel that allows organizations to measure the impact of their decisions, refine processes, and continuously improve. By linking evaluation directly to action, RI becomes a living system that informs dynamic, real-world outcomes rather than static reports.

Technology Across RI

Technology enables RI teams to scale, drive consistency, and accessibility across all aspects of RI programs. The tools an organization selects depend on its size, resources, and maturity. Regardless of sophistication, the most successful programs choose tools that are fit for purpose.

At the foundation level, many RI programs begin with freely available tools. These include agency websites, search engines, subscription alerts, RSS feeds, and shared spreadsheets or folders (see **Chapter 7**). Though simple, these tools can support strong RI outcomes when paired with disciplined processes and experienced staff. They are especially valuable for small teams just establishing their capabilities.

As organizations mature, they often adopt commercial off-the-shelf (COTS) solutions that centralize and automate certain RI activities. Examples include regulatory databases, subscription news and data services, dashboards, and workflow platforms that store documents, automate alerts, and support structured impact assessments. These systems improve traceability and enable collaboration across functions and geographies. Selecting COTS solutions often involves balancing costs, usability, and data coverage in alignment with the organization's most pressing needs.

At the highest level of maturity, some organizations invest in custom or enterprise-wide solutions that automate multiple RI activities or integrate them with other business systems. These may include bespoke RI portals, artificial intelligence tools that use natural language processing to summarize agency publications, or predictive analytics platforms that identify emerging trends from the raw intelligence data. Custom solutions are typically built when organizations require specific capabilities that are not available commercially or when they wish to integrate RI tightly with policy comment, submission management, safety reports, or quality systems.

Regardless of the tools you use, technology should support the people and processes involved in RI activities, not control them. Success depends on effective user training, strategic procurement and vendor management, robust data quality, and robust governance. As your organization grows, your tools should also evolve to remain reliable, easy to use, and aligned with your overall mission.

Using This Framework

This framework is intended to be practical and adaptable. It can serve as a diagnostic tool for assessing existing RI programs, a blueprint for building new ones, or a shared language for aligning RI functions across your organization. Applying it begins with mapping your team's current activities to the four core components: observe, communicate, evaluate, and act.

For example, a small company might use this framework to identify where activities are concentrated and where gaps exist. They may develop strong observation practices – such as consistent monitoring of agency websites – but lack effective mechanisms for evaluation or action. By visualizing their current state, they can prioritize developing communication workflows and impact assessment templates to strengthen those weaker components.

In a larger organization, the framework can help integrate multiple, discipline-specific RI programs. Mapping activities across departments often reveals duplication of effort or inconsistent terminology. Even the use of the term *regulatory intelligence* will likely have multiple different meanings within a single organization. Using the framework as a common reference helps align processes, clarify ownership, and improve information flow between strategy, labeling, policy, and quality teams.

The framework is also useful for assessing vendor capabilities. When evaluating potential partners or data providers, teams can compare different offerings against the four components. A vendor that provides high-quality monitoring (observe) capabilities but limited analytical support (evaluate) may need to be complemented by internal expertise or another supplier.

Above all, the framework is meant to be a living document. Every organization's structure, products, and regulatory context are different, and the framework should evolve accordingly. Regular reviews of how each RI component is performing can help your team stay aligned with business priorities and regulatory expectations. Adapting and refining the model over time are hallmarks of RI maturity.

Although this framework has some theoretical aspects, it is ultimately intended to be a practical tool that you can apply to your role, team, and vendors.

Conclusion

RI goes beyond simply gathering and sharing information. It is a strategic skill that brings together people, processes, and technology to enhance the development, approval, and maintenance of medical products. By observing the regulatory landscape, communicating insights effectively, evaluating their impact, and acting decisively, organizations create a cycle of ongoing learning and better decision making.

This framework provides a starting point for that cycle. It helps organize different activities and provides professionals in regulatory affairs with a common way to discuss their RI work. When used thoughtfully, it turns scattered observations into coordinated strategies that support innovation and help deliver medicines to the patients who need them.

As new technologies, faster review processes, and more global collaboration shape the regulatory environment, strong RI programs will become even more important. This framework serves as a starting point – a flexible, practical model that you can adjust to fit your team's goals and situation.

In the chapters that follow, we will explore elements of this framework in greater depth. We will examine methods, tools, and case studies that bring RI to life. By mastering these principles, we strengthen our collective ability to deliver safe, effective, and innovative products to patients worldwide.

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