REGULATORY FOCUS

Advantages of developing and deploying an in-house regulatory intelligence

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Companies with a global regulatory presence may benefit from developing an in-house regulatory intelligence database. Such a database can be customized to focus on key subjects by building content reflecting published sources and the company's experience. Adaptable content for multiple uses can be built by the company's local experts. The system structure must support diverse users to create, maintain, document, access, and understand the information with functional collaborative capabilities. The organization is informed with actionable regulatory intelligence and can adapt to rapidly changing regulatory landscapes. This article describes the processes and considerations for developing and maintaining an in-house regulatory intelligence database along with the benefits and lessons learned from a contract research organization's (CRO's) perspective.

Introduction

Access to regulatory intelligence (RI) is critical for business operations of companies such as CROs and others in the pharma industry that need to use RI in a timely manner. The complexity, comprehensiveness, and type of

information can vary greatly. The need is further compounded when working within a global framework, balancing rapidly changing landscapes across diverse regions. Expedited country measures to endorse the use of digital trials technology, stemming from the COVID-19 pandemic, exemplifies this dynamic evolution. There are numerous RI databases available either publicly or through paid subscription. There are unique benefits and challenges in complementing these resources with a dedicated in-house RI database.

It can be challenging to find adequate staffing and time for maintenance and conduct proper trainings necessary for developing and maintaining an efficient in-house database, but the flexibility and collaborative interactions allow for greater control of fit-to-purpose content in an accessible and easily updated repository. Stakeholders can identify the key topics to be included and seek out guidance from their own local country experts for structuring and updating the system. This actionable intelligence serves as a guide in supporting several types of projects throughout the drug development, market authorization, and postapproval phases.

Business requirements for users and content goals

Developing an in-house database should start with content goals in mind and by identifying the key features, collaborators and constructs of the system itself. The database should allow for adaptability to collect both traditional and emerging data through customization and a system of reviews and updates that ensure data quality and integrity. Customization allows for the data to be presented in a number of ways, for example, tables and summaries on a variety of platforms, such as Excel or Word, for easy analysis. One benefit, for example, is the ability to automate reports that are popular with users. The workflow-user interface should also be prioritized for initial entry and maintenance of intelligence. This allows flexibility for multiple workflow activities, including ad hoc updates and periodic reviews by local authors or central teams.

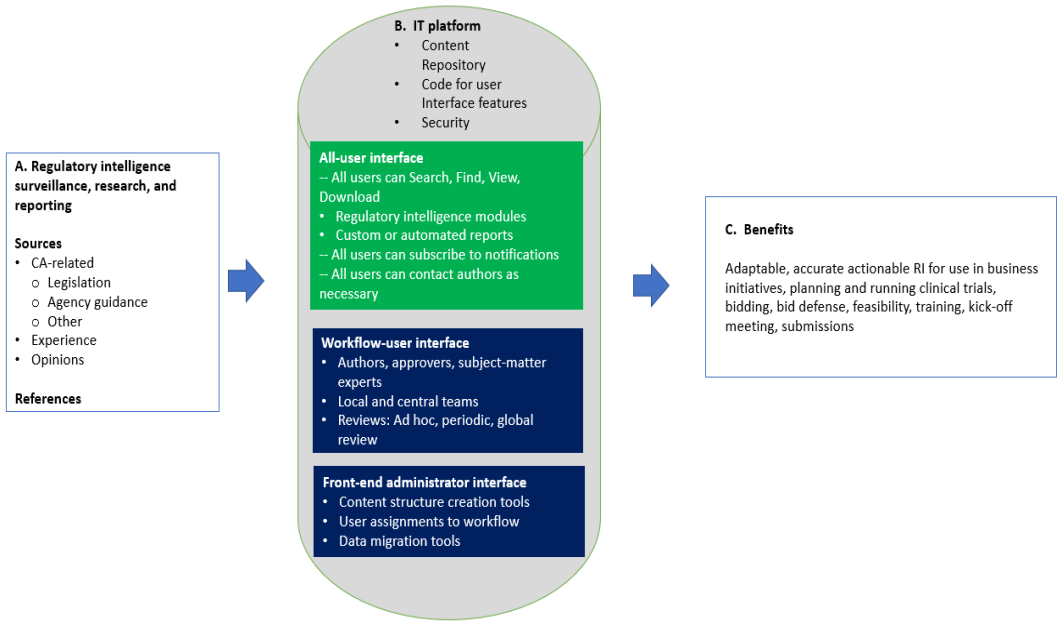
Regulatory intelligence surveillance and research

Corporate regulatory intelligence on business-critical subjects can be built from the monitoring, gathering, and analyzing of several types of knowledge, including regulations and guidance documents, expert opinions, and experience (**Figure 1A**). Regardless of the sources, there are some considerations for incorporating the date into an RI database:

- Formulate the purpose and goals with stakeholders to drive the direction of the format and content.
- Identify the internal and external experts who will provide support.
- Discuss with IT to determine what is realistic based on operating system parameters.
- Strategize and implement how the structure of the workflow system will operate.

The combined body of intelligence and collaborators from the aforementioned sources are most useful in developing a strategy for time- and cost-efficient product development and lifecycle management.

FIGURE 1 Systematically managed corporate regulatory intelligence



If the regulatory intelligence content is to be used as a basis for action, it must be trustworthy. Therefore, the content must be regularly verified as accurate and up to date. Content also should be subjected to various quality control processes. The process must be systematic and requires substantial partnership with IT to build a platform to accommodate the desired features. Basic principles for the required IT platform and other important business RI database requirements for the suggested RI system are discussed further in this article.

RI system features, considerations, and requirements

All-user interface

An essential feature should be a high-quality, front-end user experience (Figure 1B). The RI system must make the required information easy to find, straightforward to use, and should provide powerful but intuitive searching functionality.

Drop-down controversies. Much care must be taken to simplify table outputs for the intended end users. People often want a definite Yes or No answer as a basis for making actionable decisions. However, those in RA who understand the nuances of the regulations may want to answer "maybe, see comments."

Other features. Other desirable end-user features include the ability to make enquiries, download documents, and subscribe to notifications provided by the RI system.

Front-end administrator interface

The RI system should have a front-end administrator who is enabled to add new content components and authorize users who are workflow authors for their assignments (Figure 1B). The method of data entry can be essential to proper table management. The administrator must be able to organize content in the

search hierarchy and automate reports in a way that is logical and fit-for-purpose for most users.

Workflow-user interface

Flexible workflows must be designed to create a variety of workflow groups with little restriction (Figure 1B). However, each basic workflow should contain a system of checks and balances with reviewers of content. Workflow users must be given an accurate list of instructions to complete for each module. Clear guidelines need to be established upfront for consistency in completeness of information, language, and style.

Central versus local authors

Workflows are best carried out by local team authors and approvers for each country, with the help of SMEs for some content modules. In other cases, a central team could be responsible for the content.

Platform

The platform will consist of a relational database for data storage and a logical layer for most business logic and web services (Figure 1B). It also will use a front-end layer to produce the features required for the user interface.

Choice of server for the platform should be made based on the ability of the server to contain the content repository, respond rapidly and accurately to requests for information, and include search functionality by hierarchy and free text words.

Content structure

Optimizing uniformity, granularity, and searching. One key to the repository is the basic content module (Figure 1B). The module contains the RI content and represents the means to optimize granularity, searchability, and uniformity of the RI system content. One can control granularity by combining or splitting modules at the introduction of the modules. Use of tools to enhance searchability of content is recommended.

Module features. Each module should have the ability to contain rich text fields that provide the RI summaries and sources of information. Authors should be able to add revision history and set notifications about their changes. Each version saved by a workflow user should appear in an audit trail that is accessible to all users. In case of inspection, audit trails are valuable sources of information about how the content updates had progressed.

Ad hoc updates versus periodic review. RI surveillance followed by ad hoc updates is often the best means to keep RI system content contemporaneous. The system should provide opportunity for authors to start a workflow when they become aware of the need to update content. A system schedule of reminders to perform reviews at regular intervals is also warranted for all content.

Contributions to quality: Governance, training, and resources

Clear instruction is key to obtaining creating and using the system content. For example, administrators must be able to anticipate how authors will interpret directions. Authors must be well versed in their assigned areas of expertise. In addition, they should provide complete, accurate, and meaningful intelligence for the end users. Business users must understand how to use the content properly.

The majority of training is conducted outside of the system, and much of it is specific to the user group. Training for creation of content is directed at system administrator, workflow users, and the governance committee and consists of both general and content-specific training. It is the governance committee that must assure the system contains the appropriate content and the workflow is properly resourced. General workflow user training must be followed with detailed training rules for authoring specific content.

Training for use of the content also requires both general and specific components. All system users must receive introductory training to RI and use of the RI system including information about content structure, searching and exporting the content. For particular business activities specific training will be required and should include examples of how to find and use the correct content. All users can contribute to quality by determining training gaps and anticipating training necessary following launch of the new system content.

Conclusion

An interactive interface allows for a diverse group of users to access content and provide feedback or suggestions directly to the authors in order to improve the system. This collaborative effort between various departments drives the direction of the content and serves as a system of checks and balances. The resulting effect is a database of business-critical content optimized for functionality and purpose to meet business needs: the effective, compliant and timely delivery of projects.

Business-critical content can be delineated into two main categories: traditional and emergent. Traditional content can include regulations and company experience with regards to common topics such as approval timelines, informed consent, safety reporting and submissions. Emergent topics are identified through collaborative measures to meet company and client needs. This type of content – also based on regulations and experience – occurs through gap analysis identifying emerging trends and needs. It is important for stakeholders to be able to discern which emergent content should be captured and maintained. Over time, emergent content can potentially be established as traditional content.

About the authors

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Citation Schofield S, Waggoner W, Joines J. The advantages of developing and deploying an in-house regulatory intelligence database. REGULATORY FOCUS. March 2021. Regulatory Affairs Professionals Society.