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Review Article

Role Of Regulatory Intelligence In Pharmacovigilance

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ABSTRACT

In this project have given Information and regulatory documentation play inessential part in the decision-making within the company. It is particularly true in these actor of the pharmaceutical industry, in which a good risk management is essential. To find this information,to manage and to analyze, require the installation of an adapted regulatory intelligence, structured,exhaustive and relevant. Therefore, rigorous process (search of sources, data' collection, diffusion and analyze) is the necessary condition for the setting up of are regulatory environmental scanning system, as well astheadhesion of the decision makers, the collaboration of expert sand the implication of all the collaborators. This article proposes an installation diagram of a regulatory intelligence adapted to pharmaceutical industry bydetail in gets various stages until its rationing more global process of economic intelligence.

INTRODUCTION

What is Pharmacovigilance?

Medicines and vaccines have transformed the prevention and treatment of diseases. In addition to their benefits, medicinal products may also have side effects, some of which may be undesirable and/ or unexpected. Pharm covigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use. However, the clinical trial process involves studying these products in a relatively small number of selected individuals for a short period of time.Certain side effects may only emerge once these products have been used by a heterogeneous population, including people with other concurrent diseases, and over a long period of time. .

REGULATORY INTELLIGENCE

Regulatory intelligence has gained significant importance with increasingly global

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considerations for product development, clinical trials, and submissions to ensure market access in key regions. Theregulatory intelligence profession, tasked with providing strategic input to ensure regulatory compliance, has evolved to fulfill the additional needs of various departments within the company and by senior leadership by strategically analyzing relevant regulations and product competitive landscapes. The increased complexity of products and implementation of technological innovations is again changing the demands on the regulatory intelligence professional. This article provides an overview of the evolution of the regulatory intelligence profession over the past 2 decades and examine sits possible trajectory during the next 5-10 years.

REGULATORY INTELLIGENCE DEFINITION:

Regulatory intelligence is the act of gathering and analyzing publically available regulatory information. This includes communicating the implication of the information and monitoring the current regulatory environment for opportunities to shape, future, regulation, guidance, publicly and legislation.

WHAT IS NOT REGULATORY INTELLIGENCE?

1. competitive intelligence (sometimes done by the regulatory department, more often done by
2. the marketing department)
3. proprietary information
4. sales or marketing information
5. drug pricing or insurance information
6. reimbursement issues

AGENDA OF REGULATORY INTELLIGENCE:

- What Regulatory Intelligence (RI) is and why it is important to companies
- The Divisions of Regulatory intelligence and what each function provides
- Sources ofRegulatoryintelligence
- Monitoring the ever changing regulatory landscape
- Transforming regulatory information into Intelligence

WHAT IS REGULATORY INTELLIGENCE IN PHARMACOVIGILANCE?

In Pharmacovigilance (PV), Regulatory Intelligence is the act of gathering and analyzing publicly available regulatory information, communicating the implications of that information, and monitoring the current regulatory environment. Regulatory intelligence is about remaining up to date with changing regulatory requirements as implemented by governments and regulatory authorities. These apply to both medicinal products and medical devices in development and authorized on the market. This means that new or changed PV-relevant regulatory information needs to be screened and assessed routinely for potential impact on company procedures and over all pharma co vigilance strategy. An impact assessment needs to be performed and documented, and Regulatory Intelligence activities need to be communicated to stakeholders.

BENEFITS OF REGULATORY INTELLIGENCE:

- Increase compliance
- Increase like hood of marketing application approval
- Shorten time from filing to approval
- Increase efficiency
- optimize study design forregulatory endpoint
- optimize messaging about product benefit
- Maximize target market potential.

ORIGINS OF PHARMACOVIGILANCE:

The history of pharmacovigilance goes back more than 40 years. In 1965 the eighteenth World Health Assembly, WHA 18.42, drew attention to the problem of adverse drug reaction monitoring and following further resolutions (see Annex 3) in

1966, 1967 and1970 the International Drug Monitoring Programme came into being. In 2005, 78 member countries are participating in this Programmed and the last decade has seen the participation of numerous developing countries. The programmed functions on the basis of national pharmacovigilance centres coordinated by the WHO Programmed for International Drug Monitoring, which consists of the WHO Collaborating Centre for International Drug Monitoring, Uppsala and the Pharmacovigilance Department of WHO, Geneva. Recently, the concerns of pharmacovigilance have been widened to include herbal, traditional and complementary medicines, blood products, biological, medical devices and vaccines. Many other issues are also of relevance to the science of pharmacovigilance. These include substandard medicines, medication errors, lack of efficacy, use of medicines for indications that are not approved and for which there is inadequate scientific basis, case reports of acute and chronic poisoning, assessment of medicine-related mortality, abuse and misuse of medicines, and adverse interactions of medicines with chemicals, other medicines and foods and drinks.

Aims of pharmacovigilance:

The specific aims of pharmacovigilance are to,

- improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions;
- improve public health and safety in relation to the use of medicines;
- detect problems related to the use of medicines and communicate the findings in at timely manner contribute to the assessment of benefit, harm, effectiveness and risk of medicines, leading to the prevention of harm and maximization of benefit
- encourage the safe, rational and more effective (including cost-effective) use of medicines; and Pharma covigilance promote understanding, education and clinical training in pharmacovigilance and it effective communication to the public.3.3 The cost advantage medicines monitoring system is an essential and cost-efficient means of detecting and minimizing injury to patients and averting potential disaster. Pharmacovigilance can help to better assess and communicate information on the effectiveness and risks of medicines and to educate and inform patients. It is also an insurance against the undetected use of ineffective, substandard or counterfeit medicines, thus minimizing the possibility of wastage of resources. The cost of a pharmacovigilance system, compared with the cost of ADRs to a nation and to the total national expenditure on the medicines, is small (see Introduction). The idea that pharmacovigilance is a luxury, affordable only in the developed world, should be replaced by the realization that a reliable system of pharmacovigilance is essential for the rational, safe and cost-effective use of medicines in all countries and consequently for public health, and should produce clear advantages in relation to cost. Pharmacovigilance has developed and will continue to develop in response to the special needs and according to the particular strengths of members of the WHO Pharmacovigilance Program. The ultimate benefit is the safe, rational and effective use.

BENEFITSOF A REGULATORY INTELLIGENCEPLATFORM:

- Provides a holistic view of external environmental factors and internal performance data which canbe measured, base lined, reported, and prioritized for improvement
- Can help identify areas of regulatory overlap and gaps

- Assists in prioritizing Risk-based reviews based upon key performance indicators
- Facilitates Product & Service Quality improvements through the integration (i.e. "Remix") of

internal and external information sources

PURPOSE OF PHARMACOVIGILENCE:

Pharmacovigilance (PV) is a relatively new discipline in the pharmaceutical industry. Having undergone rapid growth over the past 2 decades, PV now touches many other disciplines in the research and development enterprise. With its growth has come a heightened awareness and interest in the medical community about the roles that PV plays. This article provides insights into the background and inner workings of PV.

METHODS:

This narrative review covers the core PV activities and other major areas of the pharmaceutical enterprise in which PV makes significant contributions.

FINDINGS:

Drug safety monitoring activities were organized by the US Food and Drug Administration and academic medical centres in the early 1950s in response to growing concern over the occurrence of aplastic anemia and other blood dyscrasias associated with the use of chloramphenicol. This experience was codified in the 1962 Kefauver-Harris Amendments to the Federal Food, Drug and Cosmetic Act as adverse event evaluation and reporting requirements. The ensuing decades have seen the development of core PV functions for pharmaceutical companies: case management, signal management, and benefit-risk management. A broader scope of PV has developed to include the following major activities: support of patient safety during the conduct of clinical trials through assuring proper use of informed consent and institutional review boards (ethics committees); selection of the first safe dose for use in humans, based on pharmacologic data obtained in animal studies; development of the safety profile for proper use of a new molecular entity and appropriate communication of that information to the range of relevant stakeholders; attendance to surveillance activities through a set of signal management processes; monitoring the manufactured product itself through collaborative activities with manufacturing professionals; management of benefit-risk to assure appropriate use in medical care after marketing; and maintenance of inspection readiness as a corporate cultural process.

IMPLICATIONS:.

The extent and pace of change promise to accelerate with the integration of biomedical informatics, analytics, artificial intelligence, and machine learning. This progress has implications for the development of the next generation of PV professionals who will need to be trained in entirely new skill set-to lead continued improvements in the safe use of pharmaceuticals.

GOOD PHARMACOVIGILANCE PRACTICE (GVP) & SOCIAL MEDIA

Good Pharmacovigilance Practice (GVP) at its core aims to prevent harm from adverse reactions in humans from medicines and to promote the safe and effective use of medicinal products. Pharmacovigilance professionals are aware that adverse reactions can be reported from a variety of sources – patients, healthcare professionals, competent authorities or marketing authorisation holders. Robust Pharmacovigilance however depends greatly on complete and timely reporting of adverse reactions. And herein lies the problem – it is estimated that over 90% of adverse drug reactions are under-reported.

FUNCTIONS OF PHARMACOVIGILANCE:

- Collects reports, data, ADR's etc.
- Analyses and assesses the reports.
- Promotes the safe use of drugs.
- Creates appropriate structures and means of communication needed to performitstasks.

- Identifying new information about hazards associated with medicines.
- Preventing harm to the patients.

TERMS COMMONLY USED IN DRUG SAFETY:

Pharmacovigilance has its own unique terminology that is important to understand.[5] Most of the following terms are used within this article and are peculiar to drug safety, although some are used by other disciplines within the pharmaceutical sciences as well. Adverse drug reaction is effects arising when drug given even in therapeutic dose either immunologically mediated reaction or pharmacologically mediated adverse response or idiosyncratic reaction due to the peculiarities of individual. Adverse event (AE) is a side effect occurring with a drug. By definition, the causal relationship between the AE and the drug is unknown. Benefits are commonly expressed as the patient proven therapeutic good of a product but should also include the patient's subjective assessment of its effects. Causal relationship is said to exist when a drug is thought to have caused or contributed to the occurrence of an adverse drug reaction. Clinical trial (or study) refers to an organised program to determine the safety and/or efficacy of a drug (or drugs) in patients. The design of a clinical trial will depend on the drug and the phase of its development. Control group is a group (or cohort) often individual patients that is used as a standard of comparison within a clinical trial. The control group may be taking a placebo (where no active drug is given) or where a different active drug is given as a comparator. De challenge and challenge refer to a drug being stopped and restarted in a patient, respectively. A positive DE challenge has occurred, for example, when an adverse event abates or resolves completely following the drug's discontinuation. A positive challenge has occurred when the adverse event re-occurs after the drug is restarted. DE challenge and challenge play an important role in determining whether a causal relationship between an event and a drug exists. Effectiveness is the extent to which a drug works under real world circumstances, i.e., clinical practice. Efficacy is the extent to which a drug works under ideal circumstances, i.e., in clinical trials. Event refers to an adverse event. Harm is the nature and extent of the actual damage that could be or has been caused. Implied causality refers to spontaneously reported AE cases where the causality is always presumed to be positive unless the reporter states otherwise. Individual Case Safety Report is an adverse event report for an individual patient.Life-threatening refers to an adverse event that places a patient at the immediate risk of death. Phase refers to the four phases of clinical research and development: I –small safety trials early on in a drug's development; II – medium-sized trials for both safety and efficacy; III – large trials, which includes key (or so-called "pivotal") trials; IV – large, post-marketing trials, typically for safety reasons. There are also intermediate phases designated by an "a" or "b", e.g. Phase Ibis. Risk is the probability of harm being caused, usually expressed as a percent or ratio of the treated population. Risk factor is an attribute of a patient that may predispose, or increase the risk, of that patient developing an event that may or may not be drug-related. For instance, obesity is considered a risk factor for a number of different diseases and, potentially, adverse drug reactions. Others would be high blood pressure, diabetes, possessing a specific mutated gene, for example, mutations in the BRCA1 and BRCA2genes increase propensity to develop breast cancer. Signal is a new safety finding within safety data that requires further investigation. There are three categories of signals: confirmed signals where the data indicate that there is a causal relationship between the drug and the AE; refuted (or false) signals where after investigation the data indicate that no causal

relationship exists; and unconfirmed signals which require further investigation (more data) such as the conducting of a post-marketing trial to study the issue. Temporal relationship is said to exist when an adverse event occurs when a patient is taking a given drug.

PHARMACOVIGILANCEIN DRUG REGULATION:

Pharmacovigilance programs made strong by links with regulators. Regulators understand that pharmacovigilance plays a specialized and pivotal role in product ensuring ongoing safety of medicinal products

CLINICAL TRIAL REGULATION:

In recent years there has been a substantial increase in the number of clinical trials in developed and developing countries. In their approval of clinical trials, regulatory bodies look at safety and efficacy of new products under investigation. Safety monitoring of medicines in common use should be an integral part of clinical practice. Education and training of health professionals in medicine safety, exchange of information between national pharmacovigilance centres, the coordination of such exchange, and the linking of clinical experience of medicine safety with research and health policy, all serve to enhance effective patient care. A regular flow and exchange of information in this way means that national pharmacovigilance programmes are ideally placed to identify gaps in our understanding of medicine -induced diseases.

1. **POSTMARKETING SAFETY DRUGMONITORING:**

These includes detection of drug interactions, measuring the environmental burden of medicines used in large populations, assessing the contribution of ’inactive’ ingredients to the safety profile, systems for comparing safety profiles of similar medicines, surveillance of the adverse effects onhuman health of drug residues in animals, e.g. antibiotics and hormones. The Council for International Organizations of Medical Sciences (CIOMS) repo rt on benefit-risk assessment of medicines after marketing has contributed to a more systematic approach to determining the merit of available medicines.

2. **PHARMACOVIGILANCEIN NATIONAL DRUGPOLICY:**

The provision of good quality, safe and effective medicines and their appropriate use is the responsibility of national governments. Multidisciplinary collaboration is of great importance in particular, links need to be forged between various departments of the ministry of health and also with other stakeholders, such as the pharmaceutical industry, universities, nongovernmental organizations (NGOs) and those professional associations having responsibility for education on rational use of medicines and pharmacotherapy monitoring.

3. **PHARMACOVIGILANCE IN DISEASE CONTROL PUBLIC HEALTH PROGRAMMES:**

The monitoring of medicine safety in countries where there is no regulatory or safety monitoring system in place, or in remote areas with little or no health care surveillance or infrastructure, has been identified as a matter for concern. The problems are especially apparent in situations that involve these of medicines in specific communities, for example, for the treatment of tropical diseases such as malaria, leishmaniasis and schistosomiasis, and for the treatment of HIV/AIDS and tuberculosis. Pharmacovigilance should be a priority for every country with a public health disease control programs.

COMPONENTS OF A REGULATORY INTELLIGENCE FUNCTION INPHARMA?

It begins with defining the scope (e.g., Gaps, quality), stakeholders, and communication channels. Understand the direction of the

organization and its products, build the process, then refine and measure. The value of a dedicated in-house regulatory intelligence function should not be discounted. At its core, this function is responsible for ensuring awareness and preparation in response to changes in the global regulatory landscape, although the latter [preparation] may differ in maturity depending on the defined scope, resources, and expectations of the organization for this prioritization function. Regulatory intelligence is not just data mining. Minimally, this function should be responsible for impact assessments, stakeholder identification, prioritization, regulatory trending,authoritie follow-up, and evaluation. In some cases it can also be involved in regulatory strategy or even act as the conduit for comments and responses with health authorities.

WHAT DOES REGULATORY INTELLIGENCE PROVIDE?

- Information for product teams(research)
- Supports executive strategy
- Comments on policy to shape legislation
- Track legislation
- Track. approvals, non-approvals and withdrawals
- Knowledge. management
- Training
- Creation of corporate police.

REGULATORY INTELLIGENCEPOLICY:

This function of Regulatory intelligence typically conduct the following activities:

- commenting
- government affairs
- trade group participation
- professional associations

REGULATORY INTELLIGENCESTRATEGY:

This function of Regulatory intelligence typically conducts the following activities:

- regulatory strategy, development plan or therapeutic area analysis for a product
- guidance interpretation and application
- due diligence
- Citizen's Petitions
- participation or observation of Advisory Committee or other public meeting
- defying regulatory trends and anticipating effect on company and products
- monitoring health authority organized changes
- white papers or poison statements

REGULATORY POLICY AS A REGULATORY INTELLIGENCEFUNCTION:

- Regulatory policies are created by each company to align with company goals across multiple regions.
- These regulatory policies are then implemented through exerting influence on the legislative
- process and Health Authorities by the Regulatory intelligence professional through a variety of methodologies.
- This position can be part of Regulatory intelligence, legal or government affairs.
- As well this type of Regulatory intelligence professional is proactive in influencing policy
- and shaping the landscape where as Regulatory intelligence operations monitors the landscape looking for changes and reacting to the profession.

EVOLUTION OF THE REGULATORY INTELLIGENCE PROFESSION:

Regulatory intelligence has gained significant importance with increasingly global considerations for product development, clinical trials, and submissions to ensure market access in key regions. The regulatory intelligence profession, tasked with providing strategic input to ensure regulatory compliance, has evolved to fulfill the additional needs of various departments within the company and by senior leadership by strategically analyzing regulations and product

competitive landscapes. The increased complexity of products and implementation of technological innovations is again changing the demands on the regulatory intelligence professional. This article provides an overview of the evolution of the regulatory intelligence profession over the past 2 decades and examines its possible trajectory during the next 5-10 years. Emerging technologies and systems for monitoring regulatory requirements need to be implemented to address the challenges created by the rapid regulatory developments. The scale and complexity of those developments have outpaced the ability of in-house teams of regulatory affairs professionals, which are typically small, to effectively manage compliance. Next generation regulatory intelligence systems and technologically advanced solutions have become an immediate need. Regulatory intelligence (RI), a maturing technology, is increasingly explored for its application to regulatory compliance and intelligence monitoring. The implementation of AI into state-of-the-art regulatory intelligence monitoring presents unique opportunities for surveillance, for example, of new regulatory information and formal and proposed regulations. This AI-enabled surveillance provides strategic advantages, allowing the regulatory professional to develop proactive strategy and make more efficient proactive compliance modifications, thereby reducing the burden of reactive compliance adjustments.1 In the current environment, regulatory intelligence is generally the monitoring, gathering, and analyzing of publicly available and experience-based regulatory information needed to develop a strategy for time- and cost-saving drug development. Regulatory intelligence is not just information and knowledge management. There is a need to put the "intelligence" into the collected regulatory information by conducting an impact analysis and efficiently disseminating findings to build strategies. Regulatory intelligence adds value to the information and can also help shape the environment to create a competitive advantage. An organization's ability to learn and translate that learning into action rapidly is the ultimate competitive advantage. Providing comments in response to new guidance and/or policy documents issued by regulatory agencies.

REGULATORY INTELLIGENCE PROFESSIONAL SURVEY,

1. METHODOLOGY

The fourth iteration of a web-based, industry-wide survey on the regulatory intelligence profession was conducted from 12 March to 15 April 2019. (Previous surveys were in 2002,2007, and 2013) Participant solicitation was used to ensure there was only one participant per company to obtain a cross-section of the industry and avoid multiple respondents from the same company distorting the data. Respondents accessed the 32-question survey through Google forms. It included an optional question and allowed for free-form feedback. Limitations of the survey include that the questions and participants changed during the period the surveys were conducted.

2. FINDINGS

Participant metrics. There were 38 participants in the 2019 survey, reflecting a steady increase over the previous surveys (7 participants in 2002; 14 in 2007; and 29 in 2013). Most of the 2019 respondents (71%) worked in companies with more than 1,000 employees, although smaller companies, with fewer than 100 employees, were also well represented (21.1%).Respondents indicated the number of regulatory affairs employees at their companies remained small, with more than half (55.3%) saying there were fewer than 100 regulatory affairs professionals at their company (Figure 1). The number of regulatory intelligence professionals within regulatory affairs departments was even smaller, with 52.6% of respondents indicating there were

only 1-3employees focused on regulatory intelligence at their company. Only 7.9% of respondents said there was no regulatory intelligence function, suggesting that even smaller companies recognize the importance of the regulatory intelligence function. However, the regulatory intelligence profession is likely still not sufficiently represented because only 15.8% of respondents indicated their company had more than 10 employees fulfilling regulatory intelligence tasks. The size of the regulatory intelligence function has remained largely unchanged over the last 2 decades, with about half of the respondents indicating their company had fewer than 5 employees in the regulatory intelligence function.

GEOGRAPHIC REGULATORY INTELLIGENCE COVERAGE BY RESPONDENTS AND COLLEAGUES:

Background and skillset. Regulatory intelligence professionals require a combination of knowledge about the industry and its history and soft skills. There are no hard-and-fast rules about how many years of experience a new hire would need in regulatory affairs and the pharmaceutical and/or medical device industries. However a good rule of thumb for entering the regulatory intelligence profession is that a minimum of 5 years of industry and 3 years in regulatory affairs should be required for entry-level positions. The required number of years of experience will increase with the seniority of the position.3The survey revealed that the number of years' experience in industry has increased particularly over the last 10 years. In the 2002 and 2007 surveys, the majority of respondents – about 60% – had 5 to 10 years' experience in industry, compared with about 65% of 2013 respondents and 75% of 2019 respondents having more than 10 years of industry experience. Similarly, regulatory intelligence professionals' experience in regulatory affairs also increased between 2013 and 2019, with 55.3% of 2019 respondents having more than 10 years of regulatory affairs experience, compared with 41.4%of respondents in 2013. Of note is that there was a decline from 2002 to 2019 in the percentage of respondents having worked for a regulatory affairs agency (57.1% and10.6%, respectively).

The regulatory intelligence function can have many applications within regulatory affairs and across different departments within the company but plays a key role in informing regulatory strategy. The 2019 participants were asked if they thought the regulatory intelligence function became more operational or more strategic over the last 5 years; 44% responded it had become more strategic, with only 12% indicating an increase in operational functions and 27% saying they observed. No change.

IS REGULATORY INTELLIGENCE BECOMING MORE STRATEGIC OR OPERATIONAL?

Participants were asked to rank soft skills according to their importance for the regulatory intelligence professional. The top 5 most important skills on a scale of 1 (lowest value) to 8 (highest) were negotiation, being an influencer, collaboration, communication, and, tied in fifth pace, leadership and broad industry knowledge. The rankings were very close, ranging from3.8 to 3.3, with self-motivation and strategic/critical thinking ranking lowest at 3.1 and 3.0, respectively. The closeness of the rankings suggests the value of each soft skill likely depends on personal preference and/or need during work performance. Negotiation and influencing go hand-in-hand. For example, if an regulatory intelligence professional notes changes in the regulatory landscape that would render an approved strategic plan more time- and cost-intense than previously thought, the team will need to be convinced of the benefits of developing a new strategy and altering the current development plan accordingly. Interactions with regulatory

agencies also may require negotiation on timelines and/or requirements. In addition, as noted previously in this article, policy and advocacy are becoming increasingly important in influencing and shaping the regulatory landscape. Once the regulatory intelligence has been developed, it must be communicated to the teams. The ability to communicate clearly, precisely, and using the appropriate vehicle is of utmost importance since members from diverse functional teams within and outside of regulatory affairs, as well as with colleagues at various levels within the organization might need to receive pertinent information. It was surprising that leadership was ranked as less important. Many regulatory intelligence tasks require input and collaboration from a team and some tasks cannot be done alone, making good leadership skills and working well with others important attributes for a regulatory intelligence professional. It is important to note that leadership is not dependent onan individual's hierarchical status within an organization or the size of the team. Leadership requires collaboration, negotiation, and empowering others to achieve a common goal, and therefore requires a combination of many other skills

REGULATORY INTELLIGENCE SCOPE IN FUTURE:

The survey also measured the scope of regulatory intelligence by asking participants which areas of pharmaceutical development they monitored. Regulatory intelligence professionals must cover a range of topics for which they need in-depth knowledge of the entire drug development process. In this survey, 71% of respondents said the pre-approval space and "specific therapeutic area" were the most common areas of focus for regulatory intelligence professionals. The full listing of the focus areas showed the extent of coverage needed in regulatory intelligence and included: specific product type; post-marketing; chemistry, manufacturing, and controls; competitor regulatory intelligence; pharmacovigilance; and quality. For each area of focus, at least 50% of the respondents stated it was under their purview. These results were in line with those of previous surveys.

AREAS MONITORED BY REGULATORY INTELLIGENCE PROFESSIONALS:

Deliverables, cross functionality, and key performance indicators (KPIs). There was a surprising amount of diversity regarding the deliverables for which regulatory intelligence professionals are responsible. Almost 75% of respondents stated they were responsible for developing and submitting comments on regulatory guidance documents/guidelines, providing regulatory insights on changes to the regulatory environment, educating internal groups on key regulatory topics, and contributing to the development of regulatory strategy. These results paint a disparate picture of the work done by regulatory intelligence professionals. In particular, the large percentage of respondents saying they comment on regulatory guidance documents/guidelines was a break from previous survey trends end points to policy work becoming a greater part of a regulatory professional's duties. Respondents were asked with whom or with which departments they interacted outside of the regulatory group but within their company. The most common response was senior leadership, which points to the importance of regulatory intelligence within a company. Other groups, including clinical, pharmacovigilance, nonclinical, and marketing/commercial, were also noted and indicate that regulatory intelligence professionals frequently work cross- functionally.

One organizational tool that does not seem to have been embraced by regulatory intelligence groups is the use of key performance indicators (KPIs), which measure the success or achievement of an organization or a person toward an operational and/or strategic goal. Most survey

respondents stated that KPIs weren't used within their regulatory intelligence group. Sources and communication. Regulatory intelligence sources differ across companies. Larger, better resourced companies can purchase licenses to paid subscription services such as Corelli's or Tarsus, whereas smaller companies have to rely on public sources of regulatory intelligence. The survey respondents indicated that the most popular source of regulatory intelligence was regulatory authority websites, which is understandable because they are the best source of regulatory information. It is interesting to note that the 2019 survey results indicated less usage of subscription services compared with findings in the previous iterations of the survey. That might point to there being more free information available on the internet, which reduces the need to pay for quality regulatory intelligence. Respondents were also asked about their use of social media as regulatory intelligence resources, and the most common source mentioned was professional association discussion forums, such as the RAPS RegEx platform. Surprisingly, the least-used resource was Twitter. Twitter can be difficult to use as its functionality and user interface differs from more commonly used social media sites. However, Twitter is a remarkably useful tool for competitive analysis. Frequent Twitter users can be exceptional at dissecting company press releases and highlighting key take aways. Information distribution and new tools. Gathering regulatory intelligence is only part of a regulatory intelligence professional's role. Distributing it effectively is as important. Preferred communication methods were identified by survey respondents as daily newsletters and seminars, each selected as such by 45% of the respondents. Newsletters are a common communication tool throughout the regulatory intelligence profession but can be difficult and time intensive to generate. There are vendors that create regulatory intelligence newsletters, but they tend to be expensive. This was reflected in the findings showing that most respondents generated their newsletters internally. A slight majority of respondents stated their group had used new tools and technology, such as Share point-based information management systems.

REGULATORY INTELLIGENCE OF TOMORROW:

Over the past decade, the availability of regulatory information has significantly increased, and online search engines have become more efficient. Simultaneously, availability of large amounts information creates the challenge to analyze and meaningfully arrange this information for effective dissemination. Most regulatory professionals do not have sufficient time and/or technology resources. Rapid and streamlined approaches to collating regulatory and legislative data through emerging technology, such as AI, will be needed to support regulatory intelligence professionals. Adaption to and implementation of new tools is inevitable amid the challenges in regulatory strategy and compliance. Development of AI applications and tools in regulatory intelligence is an evolving field. It is envisaged to support life sciences companies in efficiently managing modern world complexities of business overall and the regulatory environment in particular. The regulatory intelligence profession of tomorrow will continue to shift into data analytics and informatics for surveillance of the regulatory landscape. However, interpretation of insights and developing effective strategies will remain a key function of regulatory intelligence and continue to require human analysis and skills

CONCLUSION

Although the increase in availability of information is generally embraced, it also creates challenges around timely uptake and appropriate dissemination of information. Generally, PHARMACOVIGILENCE has reacted by assigning increased numbers of regulatory

intelligence professionals full or part time to monitor and inform regulatory strategies. With the increase in information availability and growing complexity, the need for using developing technology –particularly artificial intelligence, natural language processing, and machine learning – becomes more prevalent. Despite this increased need, the regulatory intelligence function currently remains small, independent of company size, which underpins the need for implementation of evolving technology to support the regulatory intelligence team.

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