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AN OVERVIEW OF REGULATORY INTELLIGENCE

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ABSTRACT:

Regulations are a common way for governments to exert control over the activities of individuals, businesses, and communities in order to promote the common good. Regulations can be for any area of society, such as environmental wellness, water or air quality, public health, or data privacy for internet safety. RI has the ability to play a significant role in assisting various stakeholders in better understanding existing regulations, their gaps and duplications, and recommending methods to strengthen them in order to streamline decision-making. Regulation Intelligence is the term we use to describe the difficulty of enabling improved comprehension of regulations. Also, Regulations are introduced as the well-being, safety, and other societal needs of citizens and enterprises. Governments also create programs aiming to improve awareness about and compliance with regulations. Goal models have been used in the past to conceptualize regulations and to measure compliance assessments. Regulations are a source of evolving requirements for products and organizations. 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, evolved to fulfill the additional needs of various departments. Regulation Intelligence is the term we use to describe the difficulty of enabling improved comprehension of regulation.

Key words : Regulatory intelligence,clinical trials, regulation

I. INTRODUCTION:

Regulatory being such a vast field of operations, often tend to create confusion for what means what. One of the most dominant services that often arrives with misapprehensions is Regulatory Intelligence (RI). Regulatory Intelligence allows the regulatory professionals to determine the requirements for global clinical trials, compliance procedures, manufacturing requirements, advice personnel, answer strategic regulatory questions and develop a global marketing application. Going further with this blog will help you have more clarity about what is Regulatory Intelligence and how it works.If you go by books there may be hundreds of words defining what RI stands for. However if you want to get the RI just remember three points

1) Collect information
2) Regulatory strategy
3) Information

In plain simple words, RI collectively comprises of three main segments which are followed while performing RI activities.[1] In general, refers to the monitoring, collection, and analysis of publicly available and experiencebased regulatory information in order to develop strategies for more time and cost-effective drug development.Regulatory Intelligence enables regulatory professionals to determine the requirements for global clinical trials, compliance procedures, manufacturing requirements, advise personnel, answer strategic regulatory questions, and develop a global marketing application using data from regulatory intelligence. Going deeper into this blog will give you a better understanding of what regulatory intelligence is and how it operates.Based on government policy objectives, regulations are introduced to ensure the wellbeing and safety of citizens and enterprises. Regulations aim to constrain behaviors of citizens and enterprises alike to achieve desired societal outcomes. Governments also introduce and manage regulatory programs, which consist of events, items, activities, or processes for ensuring compliance to regulations. Regulatory programs improve awareness about and compliance with regulations by educating regulated parties about obligations and rights in relation to a regulation, and by promoting and monitoring compliance through inspections and other means.

The concept of regulatory intelligence has its origins in the heavily regulated pharmaceutical industry. The motivation for regulatory intelligence is to enable pharmaceutical companies to remain locally and globally compliant to existing and new regulations.[2] As such, definitions of regulatory intelligence revolve around continuously obtaining and processing data and information from multiple sources and analyzing them in the relevant context. It also includes generating and communicating meaningful outputs from these data in line with an organization's regulatory strategy.This implies that with regulatory intelligence, information relating to a given compliance context and its implication can be obtained, analyzed, and communicated. The regulatory ecosystem is also monitored to identify opportunities where insight obtained from the collected information can be utilized to influence future regulations. This application of regulatory intelligence is to improve decisions making and planning for pharmaceutical companies. Goal models have been used successfully in the past to conceptualize and analyze regulations. Goal models capture the structure and intent of regulations, and enable compliance measurements andwill support the monitoring, analysis, and assessment of regulations and their supporting regulatory programs. Regulators collect and use much data while administering (i.e., introducing, enforcing, reviewing, and evolving) regulations. Judging from the numerous regulated parties a regulation can influence, these data exhibit the three V properties of Big Data (velocity, variety, volume)

Beyond the pharmaceutical industry, in other domains, the interactions between regulators, citizens, and enterprises already involve some sort of data gathering, analysis, and communication about regulations and the regulatory process. Hence, regulatory intelligence is conducted by regulators using feedback from citizens and enterprises, and compliance enforcement information to administer guidelines from the regulator's perspective, regulatory intelligence can be used to enhance the regulatory process with data-driven support for decision-making towards introducing, enforcing, reviewing, and evolving regulations. Regulatory intelligence facilitates monitoring and assessing regulations and can be used to influence the regulatory process and ecosystem.[3]

What is Regulatory Information?

- Can be oral, written, published, unpublished, etc.
- Basic building blocks of intelligence, the raw information.

What is Intelligence?

- The capacity to acquire knowledge (facts)
- Experiences (life lessons)
- ability to apply life lessons

Information vs. Intelligence

- Information is the raw data used to create intelligence; a data dump, no analysis
- Intelligence is active and related to analysis
- The data analysis and integration into company practice and procedures produces regulatory intelligence[4]

What is Regulatory Intelligence?

- "Act of gathering and analyzing regulatory information and monitoring current regulatory climate …" Regulatory Intelligence 101, M. Brown Tuttle and using this data to generate creative and innovative regulatory strategies designed to obtain and maintain product approvals in a timely and efficient manner.
- As Per the RING (Regulatory IntelligenceNetwork Group) a DIA SIAC, RI is: "The act of gathering and analyzingpublicaly available regulatory information. This includes communicating the

implications of that information, and monitoring the current regulatory environment for opportunities to shape future regulations, guidance, policy, and legislation[5]

TRANSFORMING INFORMATION INTO INTELLIGENCE

- Define your topic with key words or concepts,
- Start all searches with a checklists,
- Use different checklists for a different subject manner.
- Develop checklists for all questions.
- Checklist example is available Transforming Information into Intelligence.
- Research topic and collectall Information about your research topic from resources.
- Read Information about the research topic.
- Write a summary of each piece of information.
- Pull together all pieces of information and analyse how they fit and impact each other.
- Write up your analysis and make recommended.[6]
- Once you have summarized the information, you will need to put it in a standard format to integrate the current position and recent information to deliver information to your target audience.
- Target audience can be: – Regulatory department – Product team – General distribution to company as a whole – Management – Various departments.
- Proposed or recently codified regulation/directive/ guidance document.
- Explanation of how recent information will affect current practice and proposed changes (if any) to current practices to comply or be in-line with new information.
- How will new information affect your target audience/team or strategy.[7]

Regulatory intelligence sources and communication.

- Regulatory intelligence sources vary by company. Smaller enterprises must rely on public regulatory intelligence sources, but larger, better-resourced companies can obtain rights to paid subscription services.
- Regulatory authority websites were cited as the most popular source of regulatory intelligence by survey respondents, which is understandable given that they are the best source of regulatory information.
- It's worth noting that the 2019 poll results showed less use of subscription services than earlier versions of the survey.
- This could indicate that there is more free information on the internet, reducing the need to pay for high-quality regulatory intelligence.[8]

II. REGULATORY INTELLIGENCE DATABASES:

- Provide worldwide regulatory information (over 75+ countries) for both drugs and devices.
- Explanatory documents that guide you through country's drug/device registration process.
  - How to start a clinical trial
  - Maintenance of a clinical trial
  - Adverse Event Reporting
  - Scientific Advice
  - Orphan application
  - How to construct a market application.
  - How to deal with variations or changes of marketed products
- Use to compile, manage and archive information.
- Global regulatory information available instantly.[9]
- Information frequently reviewed can be bookmarked for easy reference.
- Documents can be printed for hard copy archival.
- Provide daily or weekly updates.
- Country specific regulations provided in the local language.
- Key word or full text searches by country of choice.
- Provide the ability to conduct focused research and surveillance, some summarizing and integration.
- Information structured logically by subject manner.
- Access to current.
- Some provide limited analysis of documents.
- SFll need to do analysis of information and impact to current program/product.

- Downloadable forms – country specific.
- Information is available in one place.[10]

List OfTop Regulatory Intelligence And Compliance Tools

1. Visualping

The tool automates the process of crawling web pages for changes. It's the world's top website change monitoring tool. Several major news publications have covered. Visualping as a tool to monitor pages online, including the Wall Street Journal, NBC and Fox News.When changes occur, Visualping sends you a real-time email alert that includes a screenshot of the highlighted changes, and a link to the monitored page. Regulatory and compliance professionals can spot the changes quickly and notify the appropriate channels.

When setting up a monitor with Visualping, users select which pages to monitor, and customize how often the pages are to be crawled. Users can monitor any pages they wish, including PDFs and social media. Depending on the urgency of the change, Visualping can crawl pages every 5 minutes to once weekly.Visualping monitors pages for **visual**, **text** or **HTML** changes.

2. Social Mention

Through **Social Mention**'s advanced search toolbar, you can produce regulatory intelligence by being alerted of specific keywords from across the internet. Social Mention checks blogs, microblogs like Twitter, images, videos and reputable news sites.

Topics to monitor include FDA changes, specific regulators, regulatory keywords, your company, competitors and the names of you and your competitors' products.You can even set up RSS feeds to easily follow developments in Feedly, featured below.RSS feeds are handy regulatory intelligence tools. As opposed to manually navigating between hundreds of websites, RSS feeds allow professionals to subscribe to a website, which sends plain-text updates to their RSS reader when new content is posted.

3. Feedly

Feedly is an RSS reader with a variety of options for monitoring data for regulatory intelligence and compliance.You can easily organize your RSS feeds by moving websites into different categories so you can efficiently identify your priorities and navigate between feeds. You can also use the tool to mark feeds as "must reads" to help ensure you won't miss important updates.

Forget emailing articles to yourself to read later. Social Mention, featured above, lets Feedly users save articles from across the web to their Feedly accounts.

4. TweetDeck

Harness the power of Twitter for regulatory intelligence and compliance. **TweetDeck** is a social media application that lets you manage various Twitter accounts.

It makes it easier to view a stream of information that automatically updates, allowing users to monitor, in a single window forlatest information, updates and search terms.

5. Evernote

Evernote lets you seamlessly save articles, documents, notes and files in one spot, making monitoring data for regulatory intelligence easier. The tool is free, with premium upgrade options.Evernote helps you keep track of important legal cases, new regulatory filings and guidance documents released by FDA. You can tuck aside background explanations of regulations you'll need to provide your co-workerslater.Check out mobile app and browser extension to easily capture your content throughout the day.

6. SCOUT

While Social Mention monitors news-related information, the tool tailored to researching government data is the Sunshine Foundation's regulatory monitoring tool, **SCOUT**.With the user's keywords, SCOUT monitors federal and state legislative data, court cases and regulatory information. While the data may be a few days delayed, it's usually the first place professionals notice new state-level legislation changes.It's also useful for tracking federal regulations, especially if you don't have time to scour through EPA, DEA, FCC, HHS, or other regulatory filings, for relevant data.

7. Federal Register.Gov

This is an obvious one. The Federal Government's regulatory publishing service, the **Federal Register**, includes several helpful features for regulatory intelligence and compliance.An example is the "Public Inspection" desk, where FDA and other agencies publish regulatory documents at least 24 hours in advance. Be one of the first to discover new regulatory developments before your co-worker's start asking questions or, start spreading incorrect information.Subscribe to RSS feeds for FDA notices. You can also subscribe to an email for the FDA's public inspection notices, as well as for other agencies.

8. Meta Reddit Monitor

Reddit is one of the Internet's most active and diverse sites. Regulatory Focus recently explained it's an excellent tool to keep tabs on developments in various disease groups, as many folks participate in active discussion groups about their particular conditions and the trials they're a part of.You can also monitor how people abuse a product, as many sub-forums are dedicated to the misuse of drugs.**MetaReddit Monitor** is an excellent tool for helping you keep tabs on hard-to-find information on Reddit.

It also supports RSS feeds. But it's a general interest website, so be forewarned you'll likely be sifting through some less-than-mediocre content before you find what you're looking for.

9. Court Listener

Similar to SCOUT, **Court Listener** is a tool that lets you monitor legal cases, but with more in-depth search options. Regulatory and compliance professionals can research more relevant legal cases, or keep up on developments affecting competitors.

Court Listener doesn't provide custom RSS feeds. But, like Visualping, it does offer custom email alerts. Free users also have access to its bulk data.

10. PubMed

Regulatory and compliance professionals need to keep up with what other professionals plan to do. **PubMed**, the National Library of Medicines' publication database, is a tool that lets you do just that.

Use its search filters to monitor publications written by select regulators or a particular office of FDA. You can also keep tabs on certain drug names and other regulator topics.[11]

III. METHOD FOR REGULATORY INTELLIGENCE:

The concept of regulatory intelligence alludes to a feedback loop in the use of data from and within the regulatory ecosystem to administer regulations. In 2013, Badreddin et al. proposed a regulatory intelligence method based on GRL that enables reasoning about regulations and compliance with regulation as a dimension. As discussed in Section 2, this method did not take regulatory programs and the amount of Big Data involved in the regulatory process, into consideration. We extend this method by incorporating a step that exploits Watson Analytics to provide a pragmatic way to explore and visualize regulations and regulatory programs as dimensions for data analysis.[12] In addition, we explore the use of Watson Analytics to analyze the Big Data resulting from the evaluated goal models of regulations and regulatory programs to gain insights about the regulatory process. Our proposal, the Goal-oriented Regulatory Intelligence Method (GoRIM), shown in Fig. 1

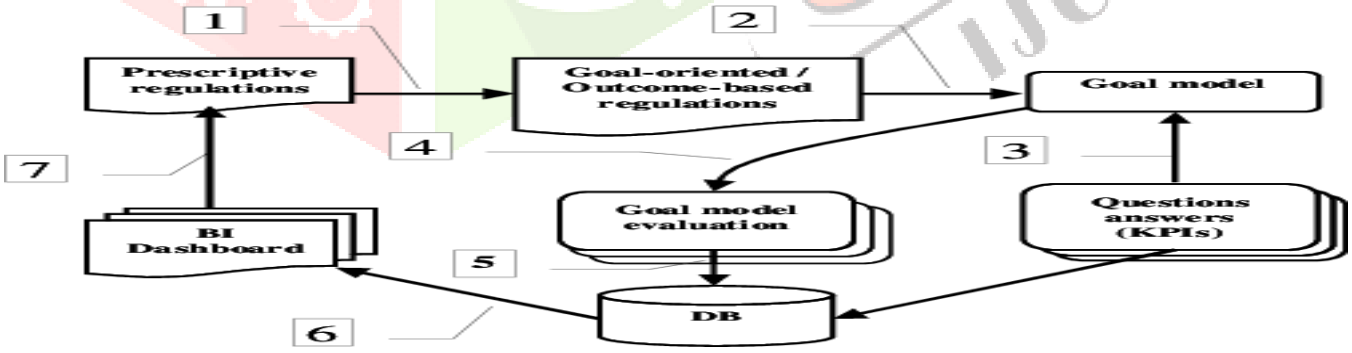

fig.1 goal-oriented regulatory intelligence method

It is inspired from the method introduced by Tawhid et al.for managing outcome-based regulations.[13]

1.As a starting point, in the first step (Build), GRL models of the regulation and of the regulatory program are built using jUCMNav, a free Eclipse-based plugin for URN modeling and analysis . These models are built using the semi-automatic method for creating goal models of regulations from tables described by Rashidi-Tabrizi et al. The same GRL concepts are used for both types of models: goals, indicators, contribution/decomposition links, actors (optional), and dependencies to resources for conditional parts of regulations/programs (optional). Contribution levels and indicators are added manually by experts to the tabular representation of the regulations/programs as they are typically not found in the original documents

2. In the second step (Select), questions to be answered by inspectors/auditors (or regulated parties themselves in case of self-reporting) during periodic compliance enforcement activities for the regulation, as well as evaluations of the regulatory programs, are selected from predefined questions so that data can be fed to the indicators in the goal models.[14]

3. In the third step (Input Data), the data collected are input to the goal models as GRL strategies. Using GRL evaluation algorithms, satisfaction levels for both the regulation and program goal models, which indicate compliance and performance levels, are computed for all goals.
4. In the fourth step (Output), snapshots of different computed compliance and performance levels can be produced for different regulated parties (companies, provinces, etc.) at different times, and stored in a database.

5 In the fifth step (Extract), the data is extracted from the database and input into a data visualization engine (such as Watson Analytics in our case). Visualizations and further analysis can be done on large datasets to enable reporting on computed compliance and performance levels and what they mean relative to the regulation and regulatory program. Based on these computed levels, the needs for reinforcements or reevaluations can be highlighted.
6. In the sixth step (Periodic Enforcement/Evaluation). Decisions can be made on specifics to focus on during the next rounds of enforcement or evaluations.
7. In the seventh step (Evolve), the needs for evolution (addition, change, or repeal) of the regulation and/or program can be triggered based on the insight gained in the fifth step.[15]

IV. REGULATORY INTELLIGENCE PROCEDURE:

The practice of delivering strategic information that underpins the making of effective and efficient decisions in relation to the regulatory aspects of the business is known as regulatory intelligence. The following activities are included in the procedure isSelection of relevant publicly available data sources, Data analysis, Generation of significant information for the definition of the regulatory strategy based on the analysis.

Three Points To Understand Regulatory Intelligence Procedure

- Gather Data
- Analyze Information
- Regulatory Strategy[16]

1. Gathering Data

There were times when regulatory specialist used to restrict RI activity to this aspect only. However when there were gaps found in the input and output, it was obvious that some important facets were missing from the shelf.To start with, RI professionals perform profound research about regulatory norms as per a particular product in a particular geography. As far as collecting relevant regulatory information is concerned, there are lot of sources that RI professionals leverage to consolidate their research material. Some of these resources can be:

- Regulatory Information on Websites, Blogs and Social Groups
- Professional Newsletters
- Competitor Product Analysis
- Seminars and Training Sessions
- Literature
- FOI Requests
- Regulatory E-mails
- Professional Networking
- Guidance Documents
- Warning Letters[17]

2.Analyzing and Processing

Since the initial phase comprises of extensive research material, it becomes evident that this data needs to be filtered out to obtain relevant information as per the purpose. You can think of it as pieces of a puzzle and now we have to make sure that all pieces fall into place to get what is necessary. An effective Regulatory Strategy communicates the right solution and encourages for proper planning within various disciplines of an organization, right from manufacturing to marketing.
This activity includes taking care of factors like the latest trends and patterns in the regulatory industry. We have been pointing out again that in order for RI to be effective, it is necessary to keep up with latest changes in regulations and guidelines. Thus it becomes apparent that this process may go through multiple modifications to screen out the obligatory outcome

3.Regulatory Strategy

The key purpose to perform the above stated undertakings is to come up with the most appropriate and practical for a company. Different products have different regulatory guidelines in different countries. This is why experts propose a plan of action that outlines an approach as to how to go about regulatory actions for the target distribution markets. However this plan of action is never a task done. It continuously goes forward as the mandates in the regulatory space change.

fig.2 regulatory intelligence procedure

In medication development, what role does regulatory intelligence play?

- Regulatory intelligence professionals provide strategic information to the drug development process; act as liaisons with regulatory bodies, and channel information to the right Ate stakeholders.
- Kirsten Messmer and Charity-Anne Schuller, regulatoRy experts, present an overview of applicable Delivery methods and general considerations for communicating information via spread-Sheets, text documents, slide presentations, strategy reports, and competitive intelligence Reports in "Regulatory Intelligence Communication for Business Impact.''
- Authors discuss how to get the most out of regulatory information when responding to specific stakeholder requests, as well as communication tips.[18]

Regulations are evolving at a faster rate than ever before

It's necessary to be on the ball all of the time.

- New technology and goods, such as the world's first 3Dprinted medication Approved recently it's possible that it won't fit well in the current regulatory context, necessitating careful adaption.

Harmonization and Expansion

- Australia is constantly implementing new EU legislation – nations may join the EU – Increased transparency equals increased accountability.
- Recent drive for transparency in the EU and the US – for example, trial registrations – More information becomes publicly available – Information overload[19]

In pharmacovigilance, what role does regulatory intelligence play?

Pharmacovigilance continuously monitors regulatory information from local, regional and global authorities and organisations for pharmacovigilance related regulatory intelligence to ensure that we and our customers are always up to speed and thereby maintain compliance with the latest regulatory requirements and guidelines;

1) Drug safety
2) That is dependable
3) Scalability should be improved.

The act of acquiring and evaluating publically available regulatory information, communicating the consequences of that information, and monitoring the present regulatory environment is known as Regulatory Intelligence in Pharmacovigilance (PV).

Regulatory intelligence is the process of staying current with new regulatory standards as they are enacted by governments and regulatory agencies. These regulations apply to both pharmaceutical drugs and medical equipment that are in development and have been approved for sale. This means that new or altered PV-relevant regulatory material must be examined and assessed on a regular basis for potential influence on corporate operations and pharmacovigilance strategy. Regulatory Intelligence efforts must be reported to stakeholders, and an effect assessment must be done and documented. PV Regulatory Intelligence is managed by ProPharma Group for a number of clients. Regulatory Intelligence is also used by our team to keep our own internal knowledge current, such as that of QPPVs (Qualified Persons for Pharmacovigilance), LPPVs (Local Persons for Pharmacovigilance), and others.[20]

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 overall pharmacovigilance strategy.[21]

Identifying Key Areas of interest

Areas of interest that are screened in Regulatory Intelligence include many aspects of pharmacovigilance. They may include the need for a PV contact person, either local or regional, or a range of requirements, such as:

- Individual Case Safety Reports (ICSR)
- Periodic Safety Update Reports (PSUR)
- Risk Management Plans (RMP)
- Pharmacovigilance System Master File (PSMF)

Gaining PV Regulatory Intelligence with ProPharma Group

ProPharma Group manages PV Regulatory Intelligence for many clients. Our team also utilizes Regulatory Intelligence to keep our own internal knowledge up to date, e.g., of QPPVs (Qualified Persons for Pharmacovigilance), LPPVs (Local Persons for Pharmacovigilance), and others.Every time we begin a new project, the Project Lead identifies which Regulatory Intelligence screening activities are needed.

Then the Regulatory Intelligence screening activities are performed. Relevant sources are screened and any new or changed PV-relevant regulatory information is identified, which is then documented. An impact assessment is performed for the relevant information. A Subject Matter Expert on the relevant area of interest may be involved in this assessment. Stakeholders are informed of its outcome and the country specific PV requirements are updated, if necessary.The Project Lead, the QPPV, or LPPV also communicates Regulatory Intelligence updates to clients or other third parties. These updates are also communicated internally to all PV employees and other interested parties within ProPharma Group.[22]

IV. REGULATORY INTELLIGENCE IN ACTION:

1) Programmed optimization.
2) Clinoptimization's Possibility.
3) Adjustment of the development plan.
4) Questions and answers, as well as a review of regulatory requirements.
5) Regulatory overview preparation.
6) Contracts for research bidding.
7) Internal and external education and training companies Alerts that are specific to your needs, as well as a newsletter.
8) Sometimes it's as simple as seeing if a particular medicine is available in other nations.

What does RI 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 policy.[23]

V. GOAL ORIENTED REGULATORY INTELIGENCE:

Goal models have been used in the past to conceptualize regulations and to measure compliance assessments. However, regulators often have difficulties assessing the performance of their regulations and programs. In this paper, we use model both regulations and regulatory programs with the Goal-oriented Requirement Language.Goal models are often used to show compliance of information systems and business processes with one or more regulations. Here, goal models exploit various concepts (such as goals, links, and actors) to assess compliance and explore what-if scenarios to address non-compliance. The rationale is that if goal models are a useful conceptualization for eliciting, modelling, and analysing requirements in order to capture alternatives and conflicts between stakeholder objectives , they can also help explore and analysecompliance. The Nomosframework , including its variations is a goal-based modelling framework used to systematically generate law-compliant requirements and support requirements analysts in dealing with the problem of requirements compliance. Secure Tropos another goal-based conceptualization that has been used to support the consideration of laws and regulations during the development of secure software systems.[24] Watson Analytics is a pioneering software system that uses cloud computing and multiple machine learning algorithms to analyze high volumes of data. Using a simple intuitive user interface, Watson Analytics enables the user to ask questions on the collected data in natural language and returns results mined from the data across different dimensions of interest. Watson Analytics understands complicated and difficult questions asked in natural language, gives evidence-based results in an appropriate visualization, and proposes related questions of potential interest about patterns, trends, and correlations. There is growing acceptance and use of Watson Analytics, and some companies have recently started using it in a regulatory compliance context. However, to our knowledge, Watson Analytics has not been used from a regulator's perspective, nor has it been used with goal models, until now.[25]

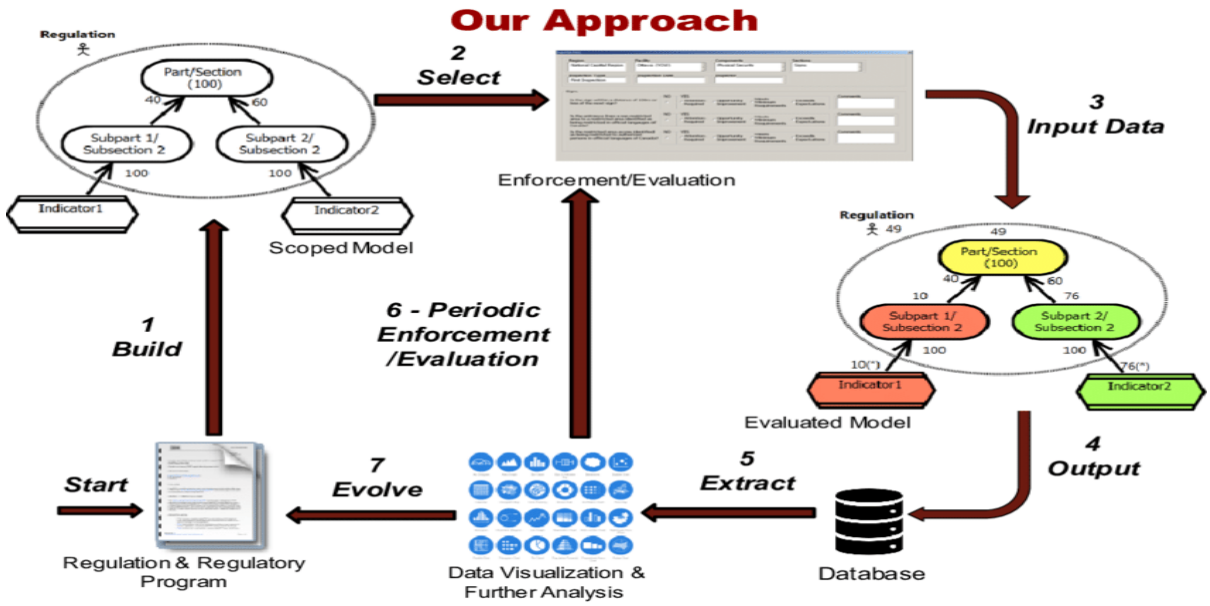

fig.3 goal oriented regulatory inteligence

VI. RI ALLOWS A REGULATORY PROFESSIONAL TO: –

- Create a strategy for a product
- Create a development plan for a product
- Research past precedence and adjust for current regulatory climate
- Advise personnel[26]

RI policy

• commenting.
• government affairs.
• trade group participation.
• professional association.[27]

RI Operation

• Regulatory Research.
• Monitoring And Surveillance Of The Regulatory Landscape.
• Drug Approval Summaries.
• Freedom Of Information (FOI) Requests.
• Newsleers
• Hot Topics (analysis of regulatory trends)
• Training
• Advisory Committee member or reviewer profiles
• Knowledge Management[28,29]

VII. IMPORTANCE OF REGULATORY INTELLIGENCE:

- Provides regulatory professionals with information to identify opportunities
- More indications and more precise pre-clinical and clinical development programmes
- Quicken development/improve efficiency
- Recognize potential pitfalls
- Issues with compliance, as well as changes in the requirements for certain indications
- Answer specific development questions posed by team RI-Predict review times for product
- Research for product teams
- Supports execution plan
- Policy comments to shape legislation
- Track legislation
- Track approvals, non-approvals, and withdrawals
- Knowledge management
- Training
- Corporate policy creation[30]

VIII. BENEFITS OF REGULATORY INTELLIGENCE:

- Increased compliance
- Increase likelihood of market inapplication approval
- Shorten from filing to approval
- Increased efficiency
- Optimize study design for regulatory endpoints
- Optimize messaging about product benefit
- Maximize target market potentional[32]

IX. CONCLUSION:

In order to cultivate regulatory intelligence and maintain compliance, you need to gather a breadth of raw regulatory data.Instead of manually scouring for this data, save time and resources with one of these top regulatory intelligence tools. Make it easier to efficiently research and analyze data so you can take action strategically and quickly.

To administer regulations effectively, a feedback loop involving data from and within the regulatory process is necessary.[33] This information exhibits the properties of Big Data, creating the need for advanced tools and technologies to enable analysis and visualization providing the insight required to make informed decisions when administering regulations and their supporting programs.Pharmaceutical companies may function more efficiently and respond quickly to any developing urgent scenario by reorganising outdated procedures and reinventing regulatory information with the help of digital technologies such as artificial intelligence. The integrated Regulatory Intelligence solution offers a more simplified ow of global

regulatory requirements by facilitating the reuse of internal data. As a result, the necessity of the hour is to imagine a connected future using digital technologies and RI. Its diverse capabilities and potential can assist pharma companies in overcoming important issues and achieving their goal of becoming a smart firm.[34]

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