

## Driving next-gen regulatory intelligence in life sciences

Data and AI-powered insights to transform regulatory decision-making



Deloitte is ushering in next-generation regulatory intelligence with an innovative solution that leverages advanced digital technologies to transform the manual and complex process of regulatory decision-making and strategy development. This solution will allow the life sciences industry to bring medicines to patients faster by improving compliance, producing higher-quality submissions, and accelerating submissions delivery.

### The challenge

The life sciences regulatory journey is a highly complex, multi-stakeholder process that requires access to timely, accurate, and relevant information. Organizations face a multitude of hurdles accessing and analyzing this information:

- **Managing and accessing global regulatory requirements is highly complex**  
*Requirements and experiences spanning 100+ local markets are disparately managed across hosts of local tools and systems*
- **Growing data volume and sources are difficult to curate and manage**  
*Extracting relevant insights from an ever-increasing number of data sources takes longer and is subject to incomplete analysis*
- **Access to internal experiences and knowledge remains elusive**  
*Experiences and tacit knowledge are most often retained by individuals and not easily accessible*
- **Regulatory intelligence activities and processes are primarily manually driven**  
*Limited advanced technology solutions exist to streamline the collection, curation, and analysis of all the data needed for informed decision-making*
- **Accessing and sharing timely, relevant, and tailored information is a challenge**  
*An increased rate of change in data and information has created additional difficulties in maintaining an up-to-date knowledge base*

### What is regulatory intelligence?

Regulatory intelligence is the collection, curation, and analysis of publicly available information (e.g., product filing, competitive information, regulations, etc.) and company-specific knowledge (e.g., interpretations, experiences, etc.) to generate insights that inform regulatory pathways and strategies.

## Our approach

Currently, the market has no mature, end-to-end regulatory intelligence solution to support the variety of needs of the industry. It is time for an innovative, digital regulatory intelligence solution with advanced capabilities to provide the information, insights, and analytics necessary for informed decision-making in the product, pathway, and submissions processes.

Deloitte's thought leadership in regulatory intelligence has been solidified through years of client engagements and life sciences industry activities, including heading a cross-industry regulatory intelligence forum. Our vision is to establish a next-gen capability powered by advanced analytics and AI technologies to transform the process of accessing regulatory information and generating meaningful insights.

## Our Vision for a Regulatory Intelligence Solution

### Regulatory Intelligence Solution

#### Regulatory Requirements

Regulatory information from legislations and health authority regulations

#### Internal Precedence

Insights in the form of past filing experience, captured via submissions data

#### External Intelligence

Insights in the form of knowledge, competitor experience, and market sensing



**Achieve optimal, timely regulatory compliance** by knowing and addressing HA requirements



**Optimize regulatory strategy** by deriving insights from up-to-date, accurate data



**Accelerate approvals** by optimizing regulatory strategies, pathways, and minimizing HA queries

Advanced capability (powered by technologies, such as ML, NLP, cognitive computing, and advanced analytics) capable of generating deep insights from requirements, precedence, and intelligence data

Deloitte is jointly working with a large, global biopharma company to bring our regulatory intelligence vision to life. We are developing the solution as a modular, highly configurable, cloud-based product to support a variety of use cases and enable companies' regulatory professionals to make AI-powered decisions at scale and with speed.

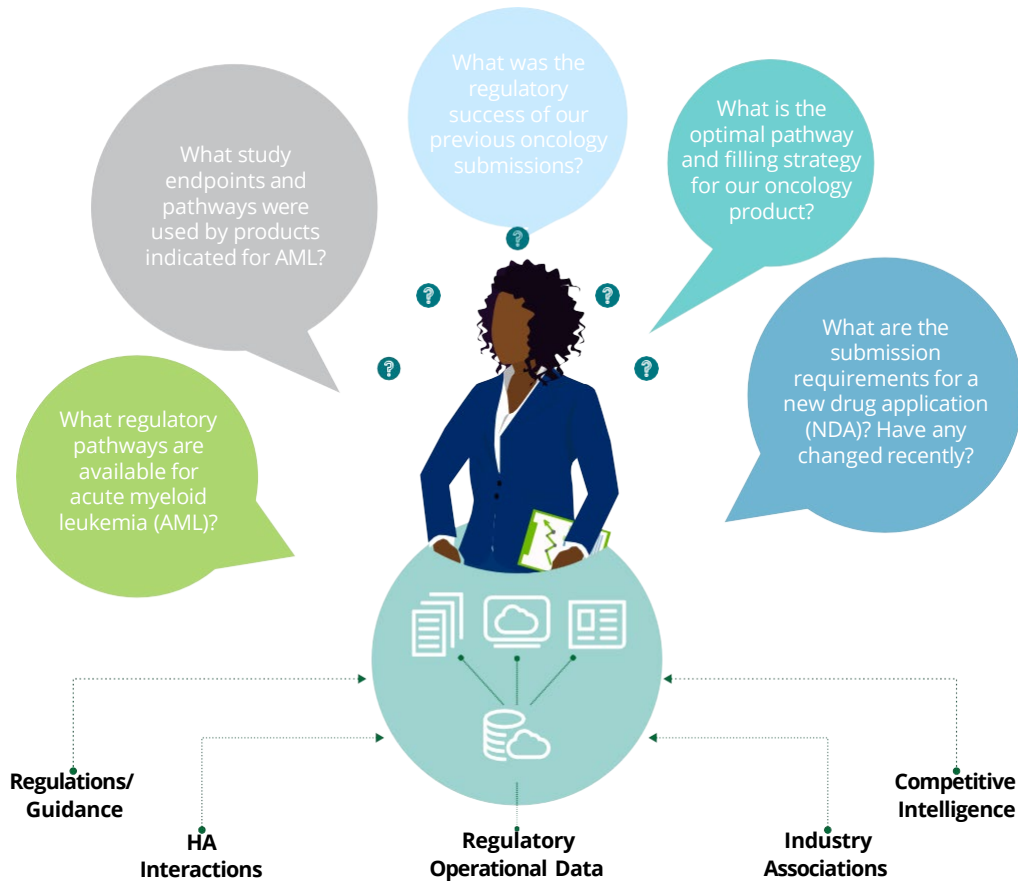


Deloitte's next-gen regulatory intelligence solution is being initially designed to enable users to manage regulatory requirements across markets, enrich the requirements with company-specific interpretations and experience, and run cross-market comparisons. Future releases will focus on collecting, interpreting, and transforming internal precedence and external intelligence data to unlock novel insights and stimulate new strategy investigations.

## Improved decisions, better strategies, and faster submissions

With Deloitte's next-gen regulatory intelligence solution, users will gain improved access to regulatory requirements across markets, AI-driven insights derived from past precedence and external intelligence data, self-service analytics, and a user friendly interface to streamline and customize the research process.

### The future state of regulatory intelligence



### Anticipated benefits include:

- 1**

**Enhanced regulatory pathways and strategies development** via seamless access to information and insights from organizational data, precedence, and best practices
- 2**

**Right-first-time submissions and faster approval timelines** via real-time, dynamic planning and access to up-to-date information and requirements
- 3**

**Minimized health authority (HA) queries** by proactively addressing regulator questions via insights from historical HA submissions, interactions, and queries
- 4**

**Possible simultaneous global submissions and optimized filings** via better understanding of global requirements and historical precedence
- 5**

**Improved organizational compliance** with local market regulations and requirements via real-time access to trustworthy information

**Real-time access to intelligence and optimized decision-making will be critical in bringing medicines to patients faster.**

**AI solutions for life sciences**

AI will likely be most impactful when deployed strategically and scaled across the entire enterprise. This is why Deloitte is developing AI offerings that span the life sciences value chain, from molecule to market. We offer a robust, integrated suite of AI-driven capabilities, solutions, and products, built on a common platform, that can help enable new transformative opportunities, drive operational efficiency, fuel business growth—and importantly—benefit patients.

Our AI solutions can help life sciences companies:

- Automate data management for clinical trials
- Improve manufacturing yield and product quality
- Leverage patient- and HCP-generated insights for product enhancement
- Power precision engagement in marketing

**Start the conversation**

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