Deloitte.

Pioneering the evolution of regulatory intelligence

Data and AI-powered insights to enhance regulatory decisions and strategies

Deloitte's innovative regulatory intelligence solution leverages advanced technologies to transform the manual and complex process of regulatory decision making and strategy development by

- **Enabling seamless requirements management** with the ability to capture company position and experience, compare cross-market requirements, and quickly generate market specific table of contents (TOCs)
- **Streamlining the management of draft and final regulation** via collaborative commenting workflows and automated impact assessments
- **Utilizing insights from past HAQs** to proactively plan for and auto-draft responses to new HAQs
- **Generating insights from internal operational data** to dynamically create/update submission plans and easily search and extract insights from past submissions, meeting minutes, or other documents
- **Analyzing industry trends and competitor information** to further inform strategies and decisions

Converge™
by Deloitte

What is regulatory intelligence?

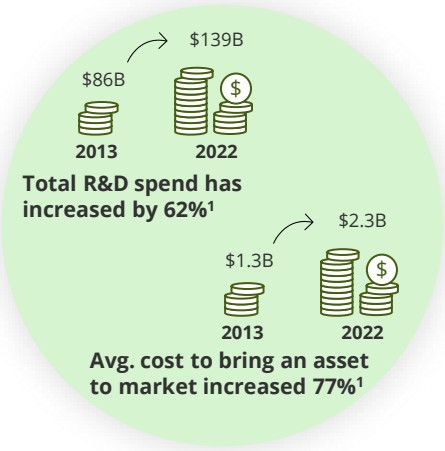
Regulatory intelligence is the collection, curation, and analysis of publicly available information (e.g., product filing, competitive information, regulations, etc.) and company-specific knowledge (e.g., interpretations, experiences, etc.) to generate insights that inform regulatory decisions and strategies. It is **NOT just a requirements repository**.

An advanced regulatory intelligence capability drives more predictive and proactive insights across the product development lifecycle to accelerate speed to market while achieving optimal, timely regulatory compliance.

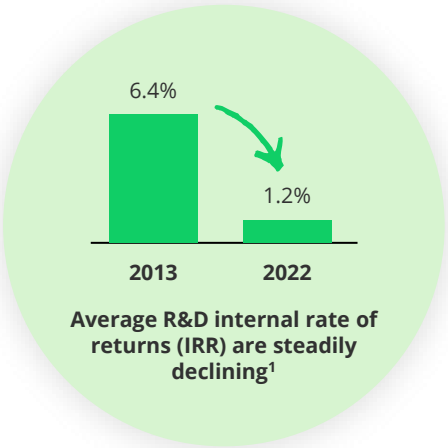
Business Drivers

A Deloitte analysis found that there are significant financial challenges in R&D

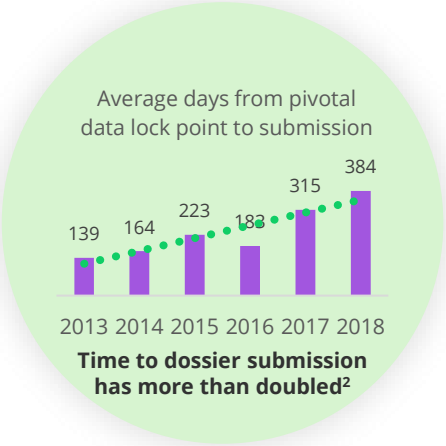
R&D costs are increasing



while returns are declining



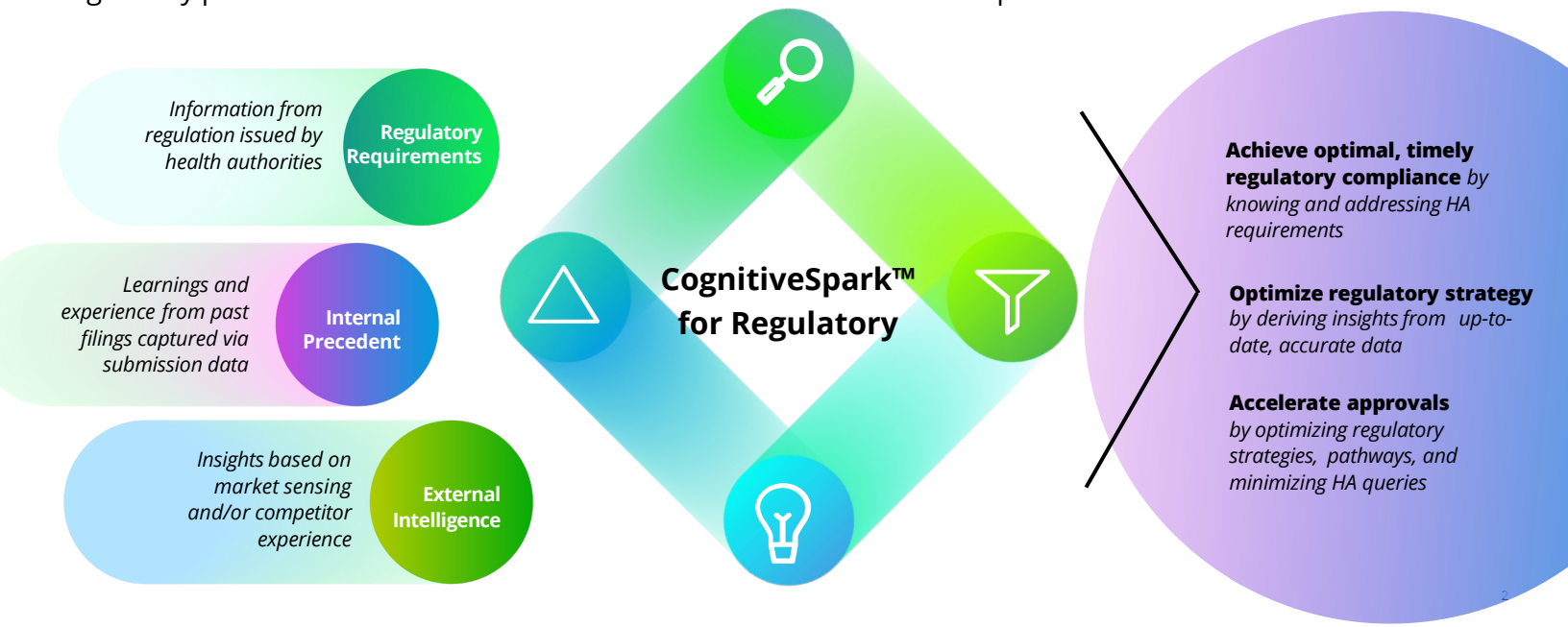
and cycle times remain long



R&D regulatory plays a critical role in bringing new drugs to markets with rapidly changing requirements. We must find ways to streamline regulatory processes to meet these financial challenges.

Our Solution

Our modular, highly configurable solution can be deployed to support a variety of use cases that enable regulatory professionals to make informed decisions at scale and with speed.



Solution modules

Each module is fit-for-purpose and can be deployed independently to support your needs. These modules will compliment your existing regulatory operational systems.

CognitiveSpark™ for Regulatory

Regulatory Requirements 1	Guidance & Regulation 2	Health Authority Query 3	Operational Analytics 4	External Intelligence 5
Seamless requirements management with the ability to capture company position and experience, compare cross-market requirements, and quickly generate (TOCs)	*Streamline the management of draft and final regulation via collaborative commenting workflows and automated impact assessments*	*Utilize insights from past HAQs to proactively plan for and auto-draft responses to new HAQs*	*Generate insights from internal operational data to dynamically create / update submission plans and easily search and extract insights from past submissions, meeting minutes, or other documents*	*Analyze industry trends and competitor information to further inform strategies and decisions*

In Use by Our Clients

Our solution addresses various business use cases

Our solution has already enabled many of these use cases with the others on our roadmap

1 Global Requirements Management
Access to accurate, comprehensive, and up to date regulatory requirements including the company position that can inform changes to the regulatory strategies

2 Cross-Market Requirements Comparison
Easily compare requirements across markets to inform regulatory strategy and submission planning

3 Experience Management
Embed experiences such as inputs form affiliates with regulatory requirements to inform regulatory strategy and submission planning

4 Draft Guidance Management
Streamlined process to respond to draft guidance via alerts, workflows, collaborative authoring, and outcome tracking to better influence final guidance

5 Regulatory Impact Assessments
Streamlined process to assess the impact of new regulation on regulatory requirements, processes, and systems via alerts, workflows, and automation

6 HA Queries & Commitment Intelligence
Auto-draft responses to HA queries or commitments based on historical responses and view trends into highly probably queries or commitments

7 Submission Plan Development & Maintenance
Create and dynamically update submission plans based on regulatory operational data from past filing experience and regulation

8 Past Precedent Library
Easily search and extract insights from past regulatory submissions, meeting minutes, or other documents to inform future HA interactions and submission planning

9 Longitudinal Product View (internal)
Generate an interactive view of the regulatory history of a company product (e.g., completion of clinical trials, submissions, HA decisions)

10 Longitudinal Product View (external)
Generate an interactive view of the regulatory history of a non-company product (e.g., completion of clinical trials, submissions, HA decisions)

11 Market Sensing
Generate trends, hints, and speaking points regarding regulations, industry, or real-world evidence to better influence policy in industry forums, HA meetings, workshops

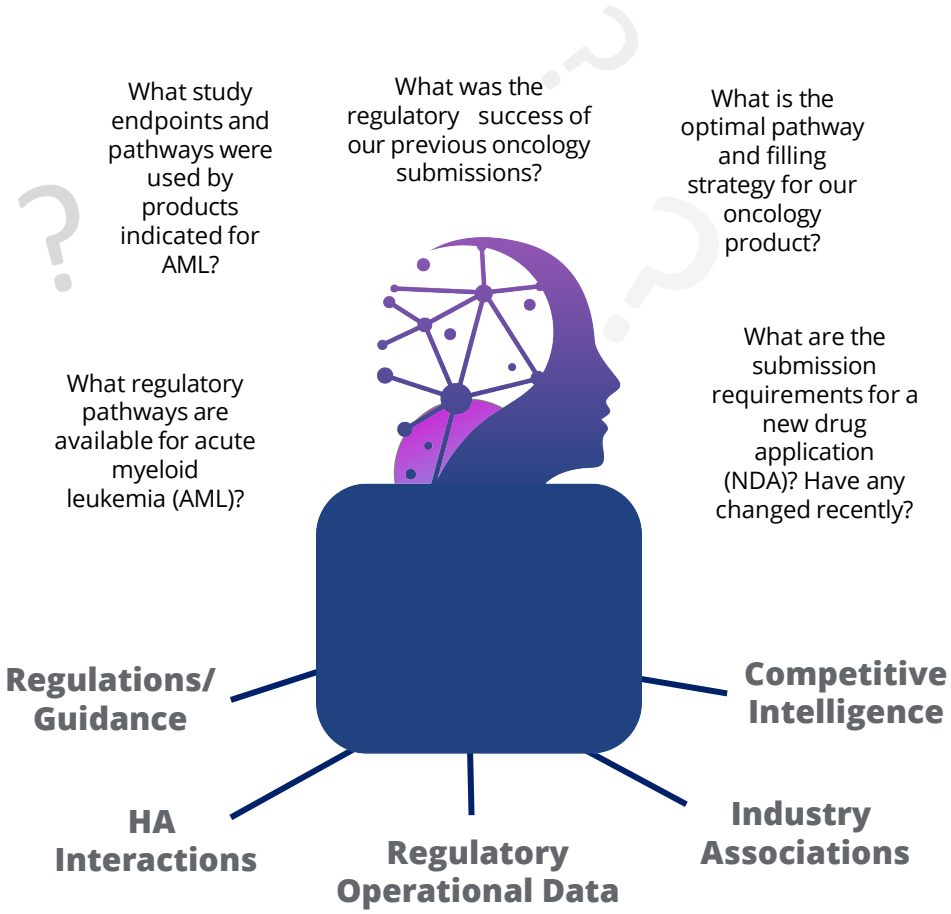
12 Competitor Intelligence
Easily search or query publicly available competitor information with ability to add additional context or implications to inform pathway decisions

13 Conferences Dashboard
View, search, and receive alerts regarding past / upcoming conferences including colleague attendance, materials, and/or synopses)

14 Regulatory Strategy Development
Generate a draft strategy based on relevant requirements, past precedent, metrics, market trends, etc. to inform regulatory strategy, submission planning, etc.

The future state of regulatory intelligence

We envision a future state of regulatory intelligence where regulatory personnel can leverage a single solution to ask a variety of questions to quickly access relevant information with tailored insights across regulations, precedent, and external intelligence



Real-time access to intelligence and optimized decision-making

will be critical in bringing medicines to patients faster.

Start the conversation

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[1]Deloitte LLP, 2022, "Measuring the Return from Pharmaceutical Innovation 2022"

[2]Benchmarking data points (pivotal data lock point, submission date, approval date) obtained from a review of publicly available data sources (FDA.gov / Clinicaltrials.gov / Ema.Europa.eu) across 19 companies for 45 unique FDA or EMA applications.