



Regulatory Information Management

Transforming Regulatory Intelligence and Submission Planning

Sep 7, 2022



OVERVIEW

About Orion

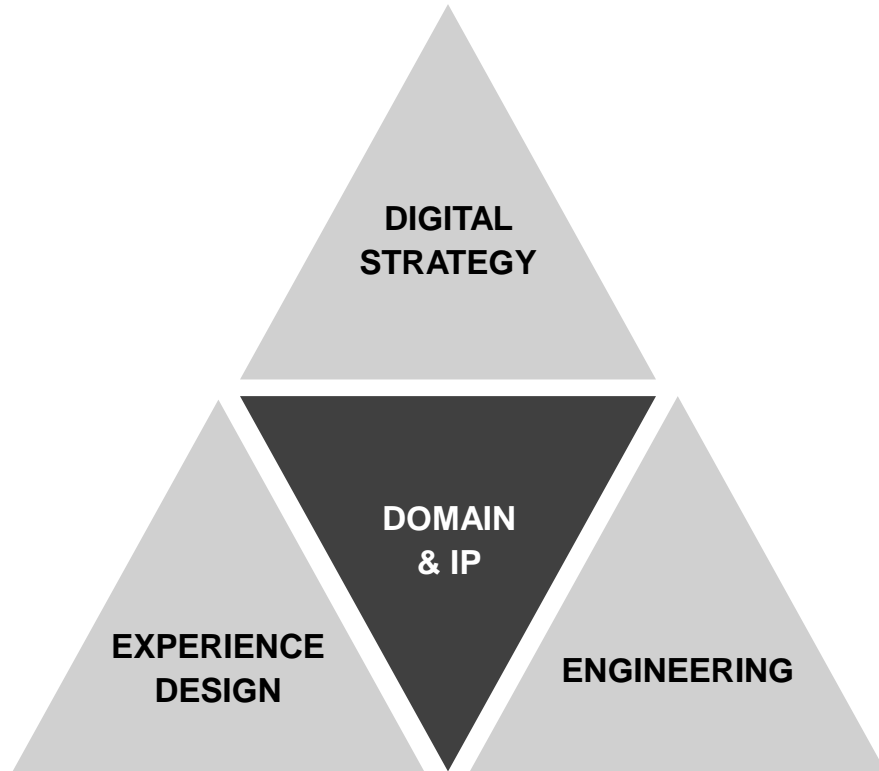
What We Do

Orion is a leading **digital transformation** and **product development** services firm. We have **deep domain expertise** across Financial Services, Professional Services, Telecommunications, **Healthcare and Life Sciences**, Sports, and Industrial IoT.

We deliver transformative business solutions rooted in **digital strategy**, **experience design** and **engineering**. Our global team of **~6,000 associates** is spread across **11 delivery locations** throughout the **Americas, Europe and APAC**. With over **25 years** of experience and a unique combination of agility, scale and maturity, our clients can operate with **agility at scale**.

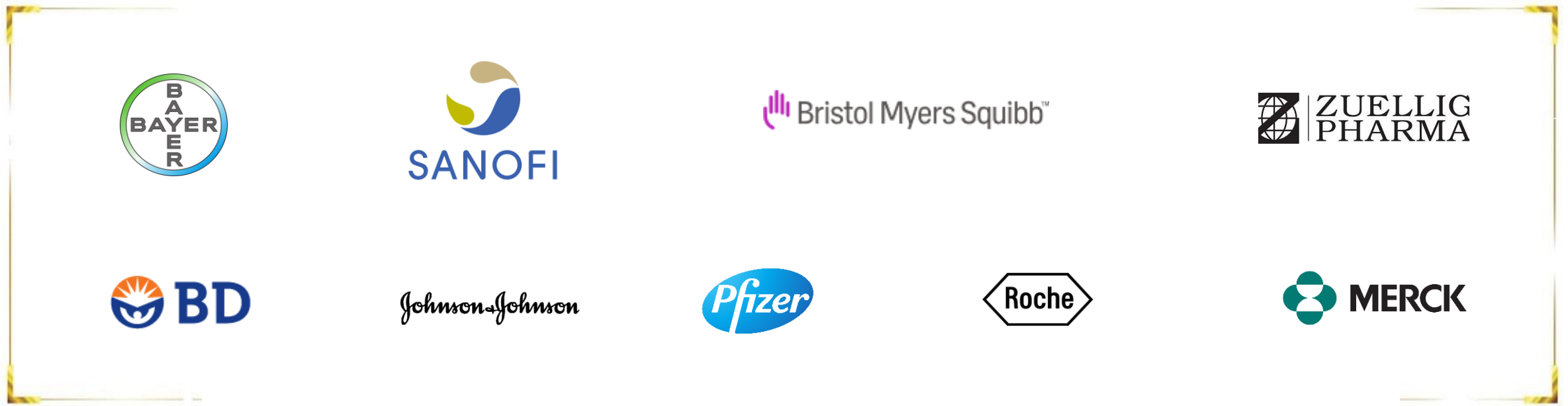
Mission

Our mission is to serve as an **agile and trusted partner** for **business transformation initiatives**, providing deep emerging technology, experience design, and domain expertise.



Watch our Corporate Video: [Transformation Stories](#)

WORKING WITH THE INDUSTRY'S BEST



“

We have been working with thought leaders from pharma, biotech, and medical device companies capturing the requirements to support the industry.

”



ReALM[®]

Overview

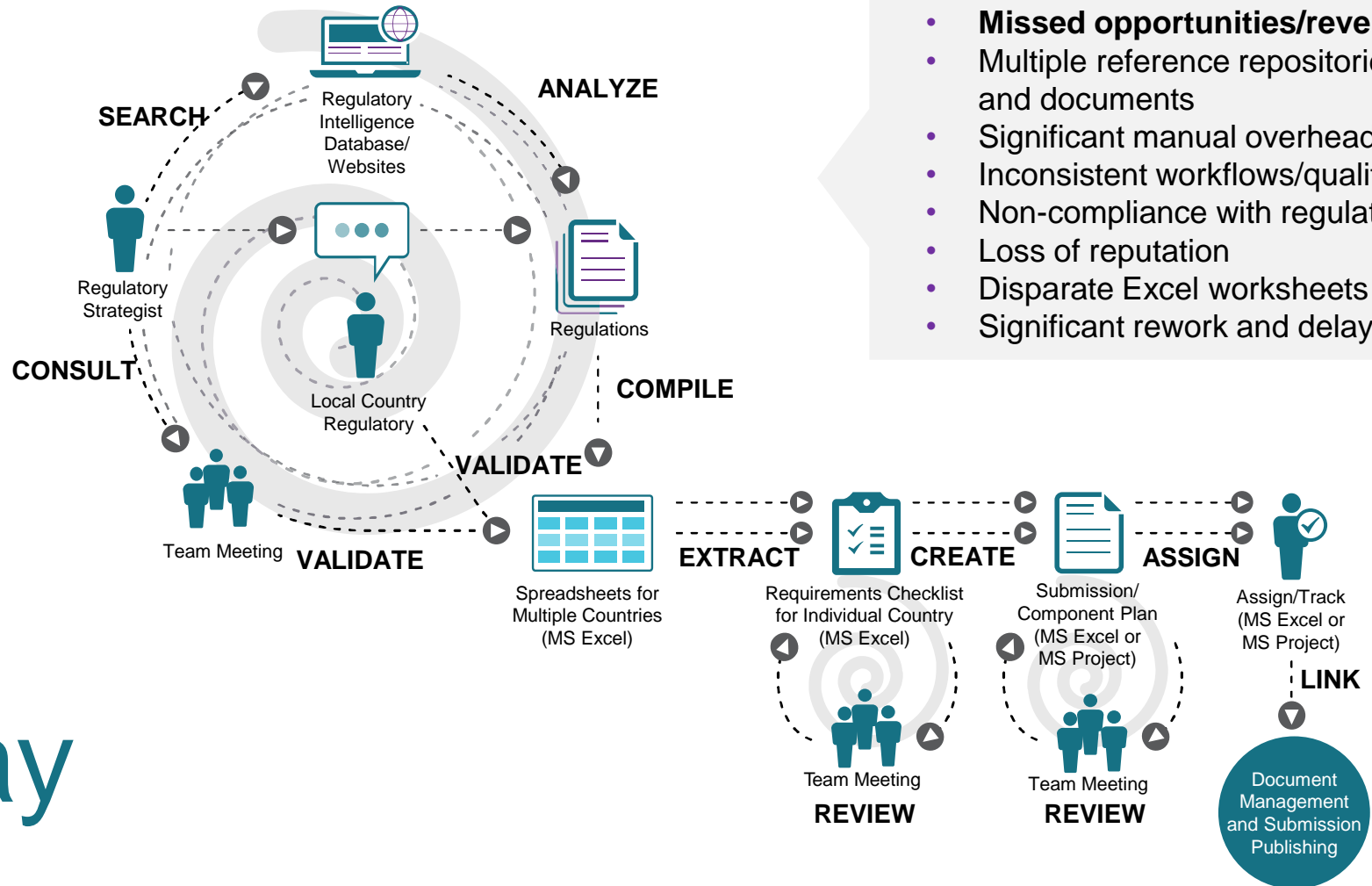
Regulatory Teams are Facing Many Challenges...

- 1 Rapidly evolving and diverging regulations introduce complexity and compliance challenges
- 2 Regulatory budgets are decreasing, but workload is increasing
- 3 Upgrades, migrations and implementations can be painful (costly, risky, time-consuming, etc.)
- 4 Historical perception that regulatory systems are rigid and not user-centric
- 5 Across R&D IT, systems are not well integrated and rarely communicate

DAILY CHURN IN THE LIFE OF REGULATORY

Daily Churn in the Life of Regulatory

- Missed opportunities/revenues: \$1M/day
- Multiple reference repositories of guidelines and documents
- Significant manual overhead and interactions
- Inconsistent workflows/quality of information
- Non-compliance with regulations
- Loss of reputation
- Disparate Excel worksheets
- Significant rework and delays

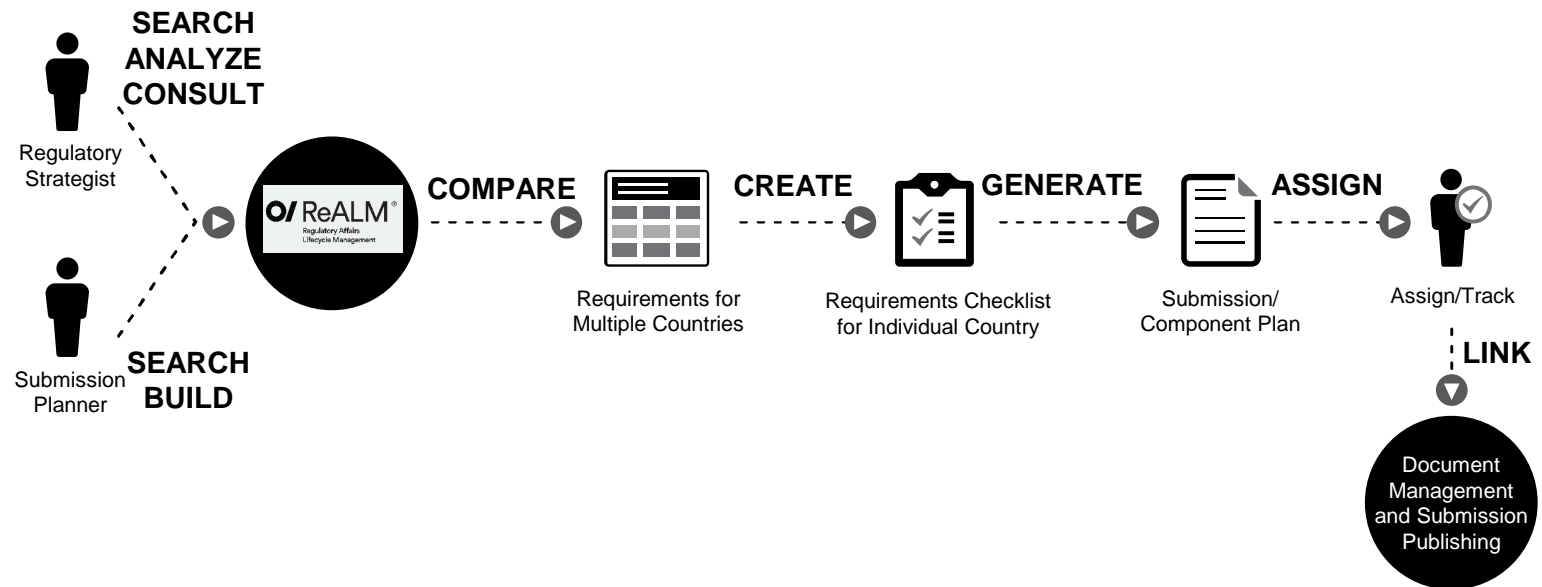


Today

Get a GRIP on RIM. Life of Regulatory with ReALM®

Regulatory Affairs
Lifecycle Management

- Integration of high-quality regulatory requirements and local interpretations into actionable templates, **checklists**, and submission plans
- Consistent workflow and view of information across regulatory strategy and planning phases
- Increase speed to market
- Reduce cycle time/rework by 25%
- Increased compliance with changing regulations
- Reduce cost of ownership of multiple tools



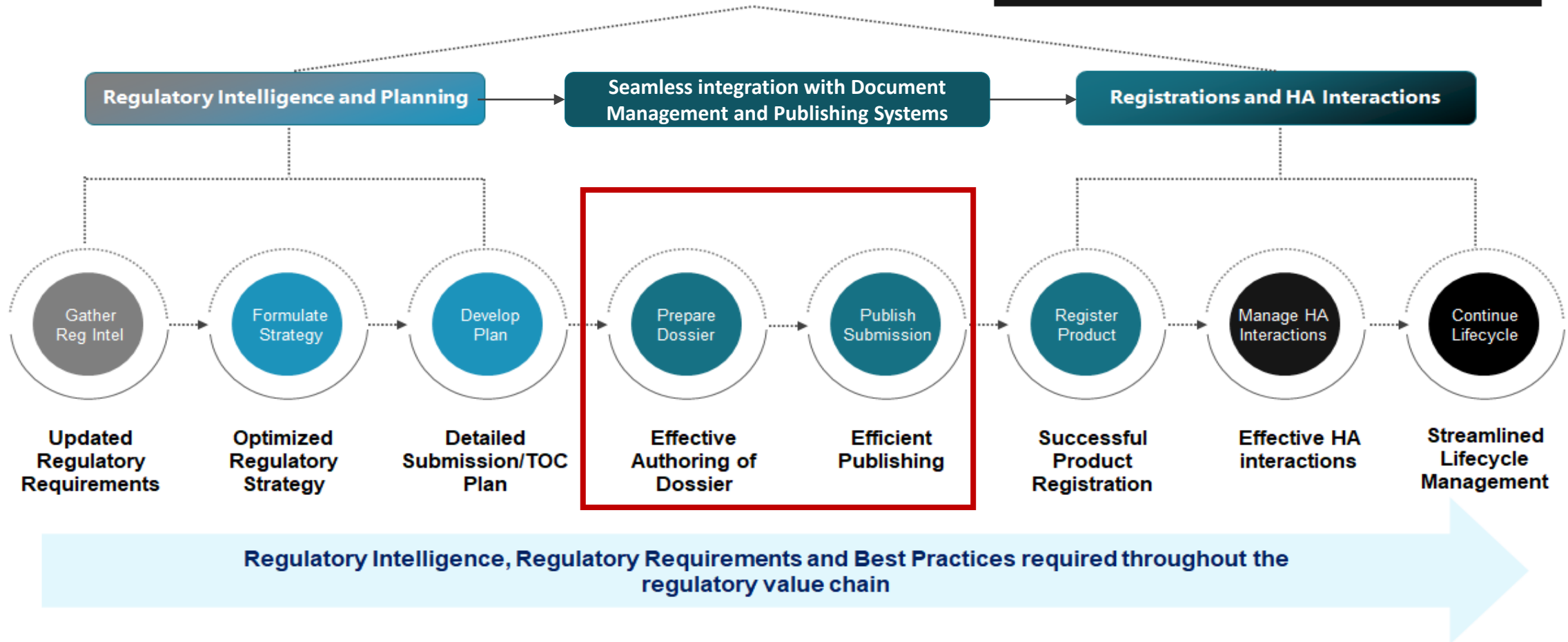
Tomorrow

INNOVATION IN REGULATORY INTELLIGENCE

REGULATORY INTELLIGENCE DRIVEN TRANSFORMATION OF REGULATORY INFORMATION MANAGEMENT



- Registered with the USPTO
- Featured by Gartner and Gens & Associates



ReALM[®] - A regulatory information management platform



ReALM[®] Regulatory Intelligence

Manage global Regulatory Requirements and Intelligence



ReALM[®] Submissions Planning

Manage global submissions and content plans



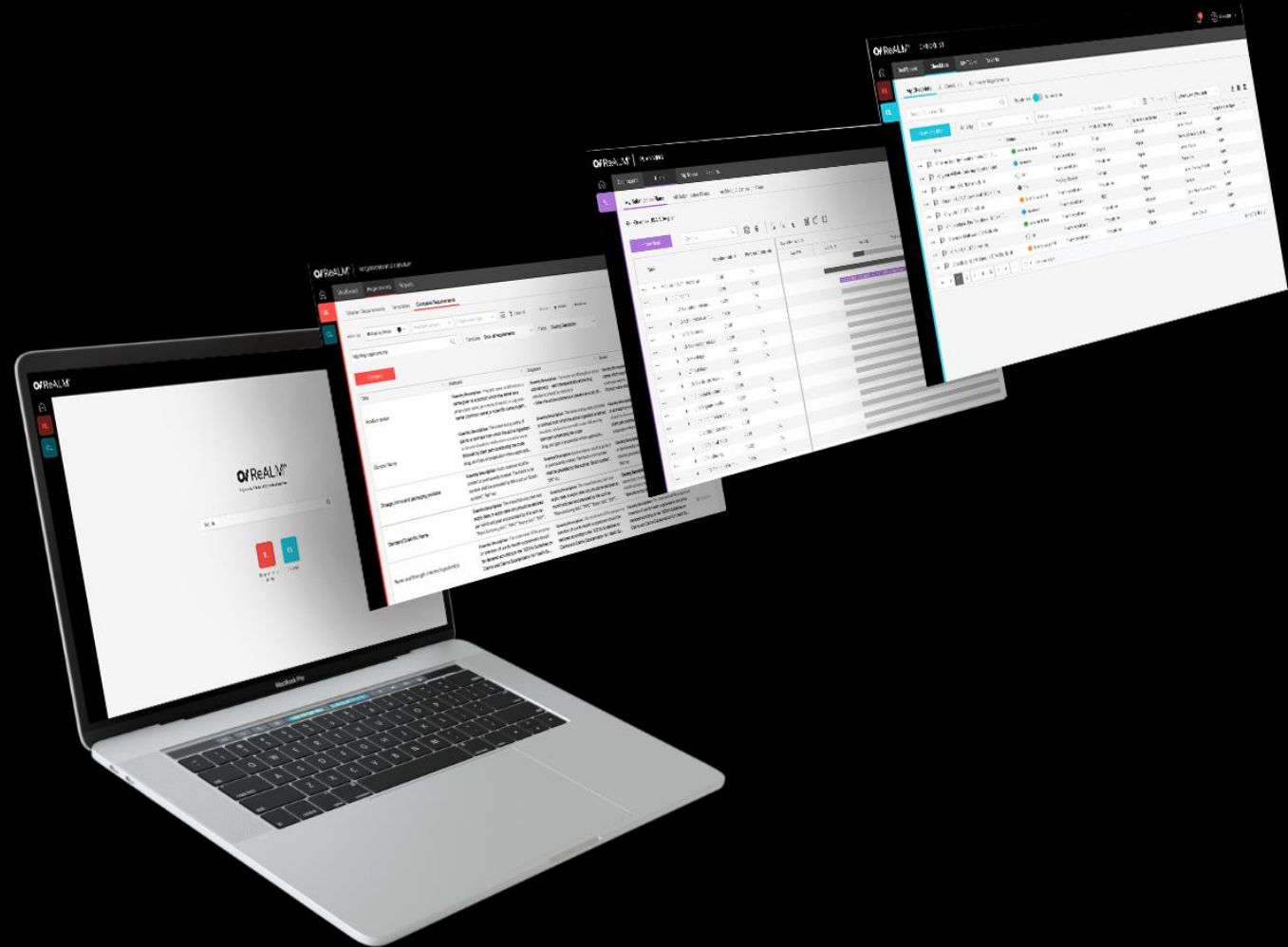
ReALM[®] Registrations

Manage product registrations and lifecycle management activities



ReALM[®] Interactions

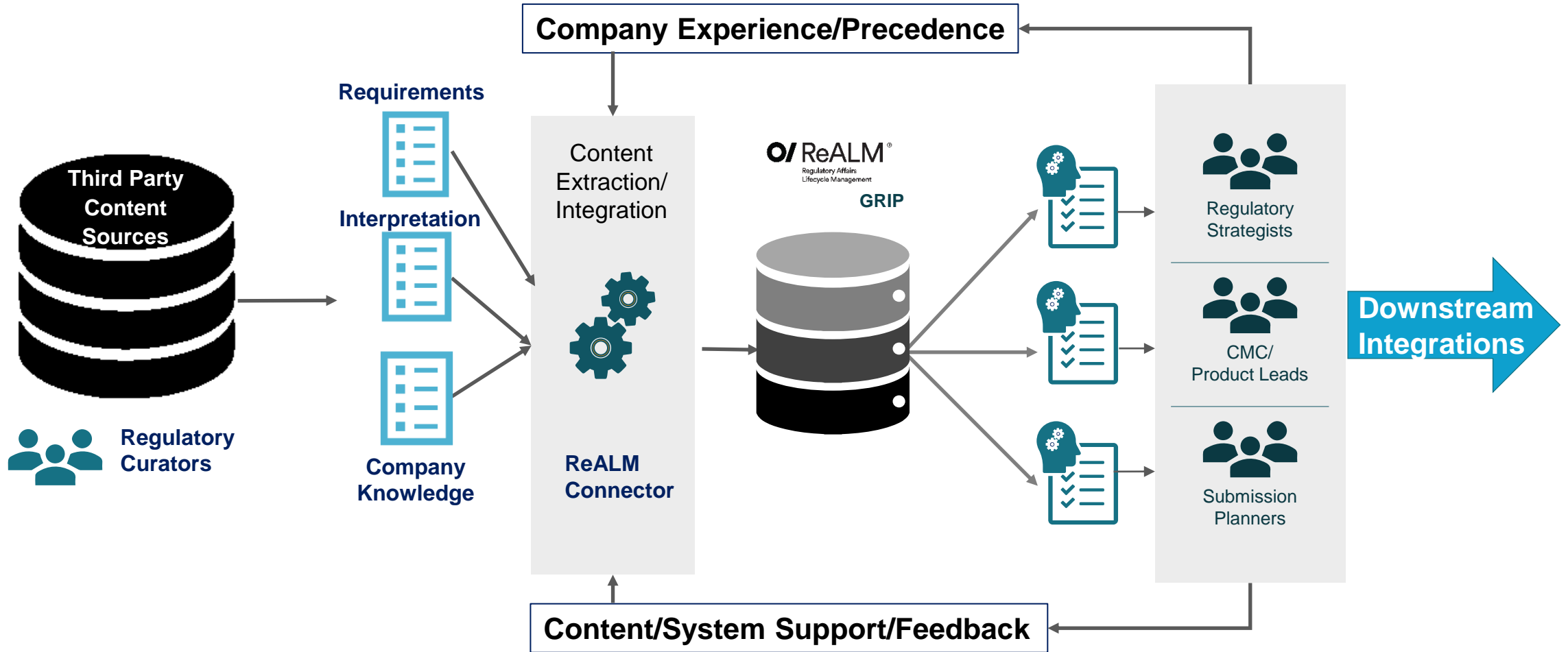
Manage health authority interactions information requests, correspondence and commitments





ReALM[®]
Solution Approach

INTEGRATED OFFERING: REGULATORY REQUIREMENTS, INTELLIGENCE, AND PRECEDENCE AS A SERVICE



Configurable and Scalable Solution



Gold Cloud Platform
Gold Data Analytics
Gold Application Development
Gold Datacenter



Actionable Insights Regulatory Strategy and Submission Plans

CONTENT CURATORS

Regions (NA, LATAM, EU, APJ, ME&A)



Countries (US, CAN, SIN, AUS, JP, etc.)



Application Types (NDA, MAA, IND, CTA, Supplement)



Master Library of Global Requirements



Outline/Template Management

ICH CTD NDA Outline



ASEAN CTD NDA Outline



CMC Supplement Outline



Labeling Outline



CONTENT CONSUMERS

Product Category



Submission Checklists

Regulatory/CMC/
Labeling Strategists
Submission Planners

Products



Submission Plan

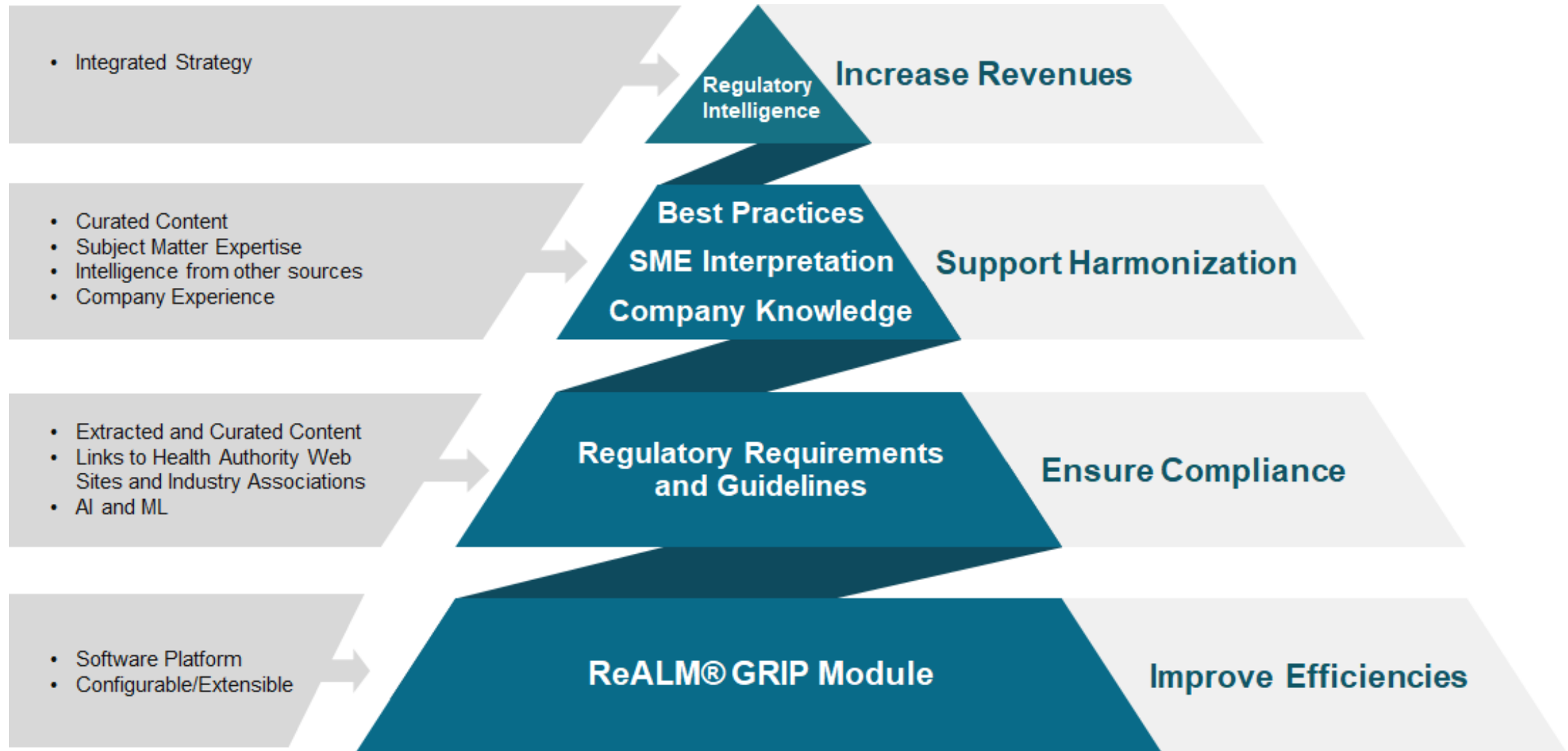


TOC Plan for US/CAN NDA

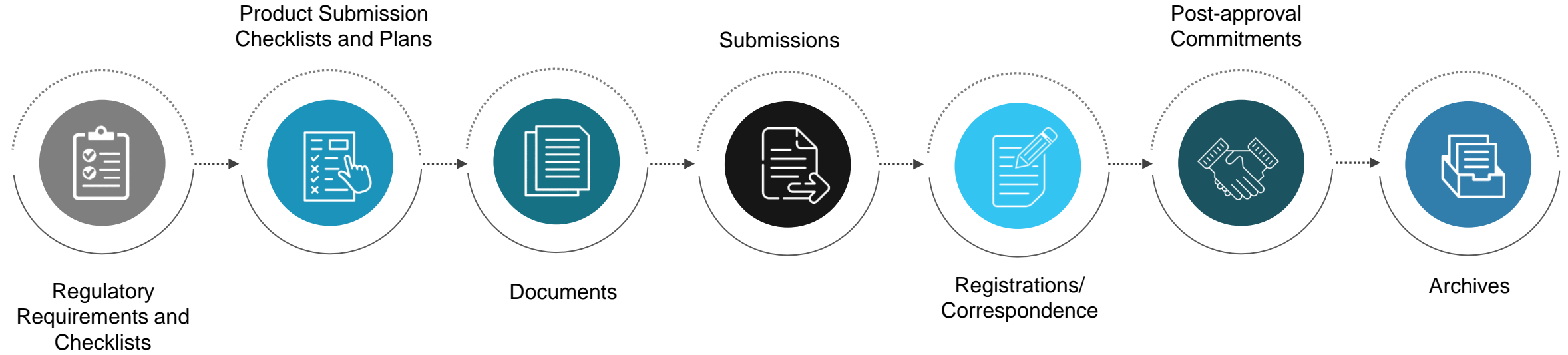
TOC Plan for SIN NDA

TOC Plans

INTEGRATED VALUE PROPOSITION – BEST OF TECHNOLOGY WITH THE BEST OF CONTENT



INTEGRATED END-TO-END RIM DRIVEN BY REGULATORY INTELLIGENCE



ReALM[®] API enables integration with downstream applications

R&D Analytics Platform based on ReALM[®] architecture for R&D Data Integration and Analytics

Thank you



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