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INTELLIGENT LIFE SCIENCES

Redefining Regulatory through Intelligent Automation

Most people in Regulatory Affairs chose the profession to help patients.

Not because they love data entry.

Yet many are awash in a sea of data, and swimming against the tide.

There is a better way.

Intelligent Enterprises ride new wave of Regulatory automation. Others risk drowning in a sea of data.

A new wave of intelligent tools and techniques is revitalizing Regulatory. Some life sciences companies are ready to jump on board and gain efficiencies. Others may find themselves barely able to stay afloat.

The tools and techniques include analytics, robotic process automation (RPA) and artificial intelligence (AI) methodologies such as machine learning and natural language processing. Their value comes through partnership with technology collaborators and innovators who are painting a more nuanced portrait of human health that regulators will need to see.

The tsunami of Regulatory data floating around organizations includes registration data, research and product data and health authority correspondence.

The goal of Intelligent Automation is to make data work for Regulatory professionals, not the other way around. With a new toolkit and skill set, Regulatory professionals can rebuild their strategic influence in life science organizations.

They will return to what gets them out of bed in the morning, shaping research and development for the benefit of patients.

This is Regulatory redefined.

It's how the Intelligent Enterprise will dictate future growth in life sciences.

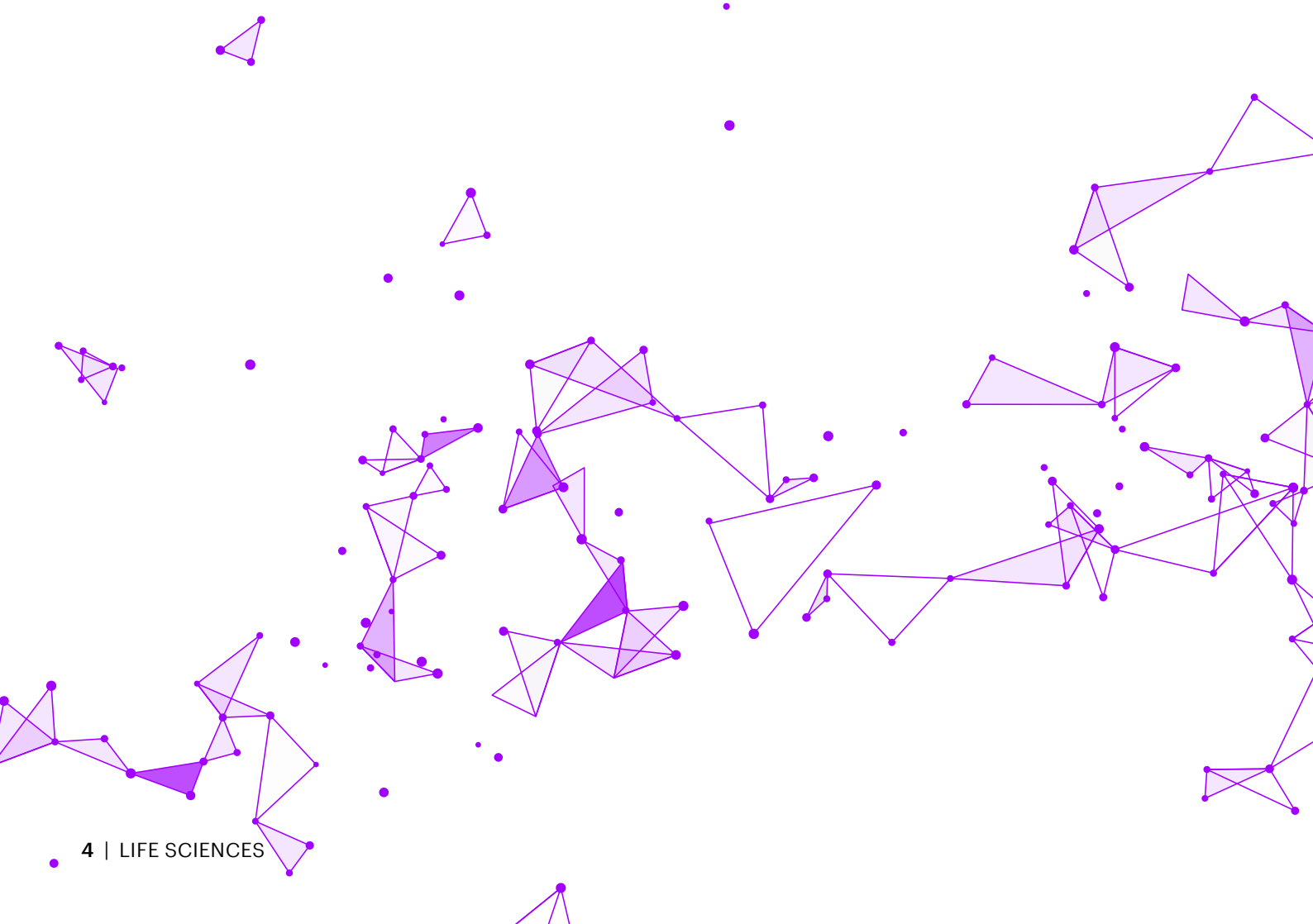
Just one-third of life science executives have high confidence in their data.

However, according to Accenture research, most organizations are still struggling to understand and assure the basic "truth" of the data they use and exchange with others.

The Accenture Technology Vision survey found just one-third of 103 life sciences executives have high confidence in their data and validate them extensively. One in four executives said they validate data sources to some extent and believe there is a lot more they need to do to ensure data quality.

There is greater urgency now because their companies will need more real-time and near real-time data to drive critical business decisions.

To confirm data veracity and increase confidence, Regulatory needs to change the way people collect, curate, interpret and apply data for submissions.



In the future, the Intelligent Enterprise will follow these 4 steps to make this change:

1. Collect

Utilize cloud-based solutions with global access that facilitates one repository with a single source of truth and eliminates the use of local file sharing and servers. Integrate applications across the end-to-end value chain eradicating data entry duplication.

2. Curate

Apply data standardization and master data management to define the right granular level of data for storage. Implement robust data governance and management to maintain data quality and integrity. Ensure traceability of data evolution, as well as end-to-end transparency of submission status and its components.

3. Interpret

Use readily available data to drive business decisions and optimize operations. Apply analytics to past submission data to recommend future submission content plans and pre-empt and mitigate health authority (HA) questions.

4. Apply

Use stored data to intelligently create submission documents. Limit documents full of free text fields and subjectivity to adopt a more digitized approach, where document templates can be compiled automatically from available data. Make real-time data accessible to the consumers of the information when and where it's needed. Manufacturing scheduling can be optimized, and batch release decisions more informed. Healthcare practitioners can get the most up-to-date product information at their fingertips.

Some companies have taken a few of these steps. Others are a long way off. By failing to embrace the opportunities offered by new technologies, they have no way to unlock true data value.

Confirming data veracity is necessary for realizing the full benefits of AI. The low confidence in data revealed by the Accenture Technology Vision may explain why the survey also found that 85 percent of life sciences executives say that AI is advancing faster than their organization's pace of adoption.

There is a clear imperative to accelerate progress. Over the next few years, life sciences companies must be ready to manage increases in the volume and complexity of new products coming to market.

The industry's late-stage pipeline is forecast to be sustained at a minimum of 40 New Molecular Entity approvals annually over the next five years.

The opportunity for introducing and growing Intelligent Automation in Regulatory has never been greater; and the need, never more relevant.

Here are some common use cases, showing how Intelligent Automation is changing the game:

Regulatory Requirements & Content Plans

Problem

Maintaining data on submission requirements is a constant challenge. As a result, market requirements gathering is often repeated for each submission, leading to longer lead-times. Additionally, insights gained from HA feedback are not incorporated into submissions, reducing first-time submission approval accuracy.

Solution

Submission contents are suggested using analytics and AI, which analyzses past submission activity and previous HA interactions.

Benefits

- Reduced time and effort with submission preparation
- Increased consistency of filings
- Improved right-first-time filing accuracy and fewer HA questions

Health Authority Correspondence Processing

Problem

Timely recording of submission approval dates or tracking of HA questions can be challenging when information received by affiliates needs deciphering and translating before being entered into Regulatory systems.

Solution

AI tools can translate and decipher letters without the need for local affiliate intervention and automatically enter information in Regulatory Information Management systems for stakeholders to act upon.

Benefits

- Same day entry of submission approvals and HA question tasks
- Reduction in effort equating to a $1mil saving per 10,000 submissions
- Increased compliance and regained system confidence

Label Authoring and Tracking

Problem

Managing and providing traceability of the roll out of global label updates is onerous based on language nuances, implementation considerations and replicated data terms across multiple documents. Leading to a high risk of product label inconsistencies.

Solution

AI tools can take the complexity out of mapping global-to-local terms and provide end-to-end traceability.

Benefits

- Reduced effort of reviews and hand-offs to multiple affiliates
- Increased speed in getting updated information to patients
- Improved compliance with a single source of registered information

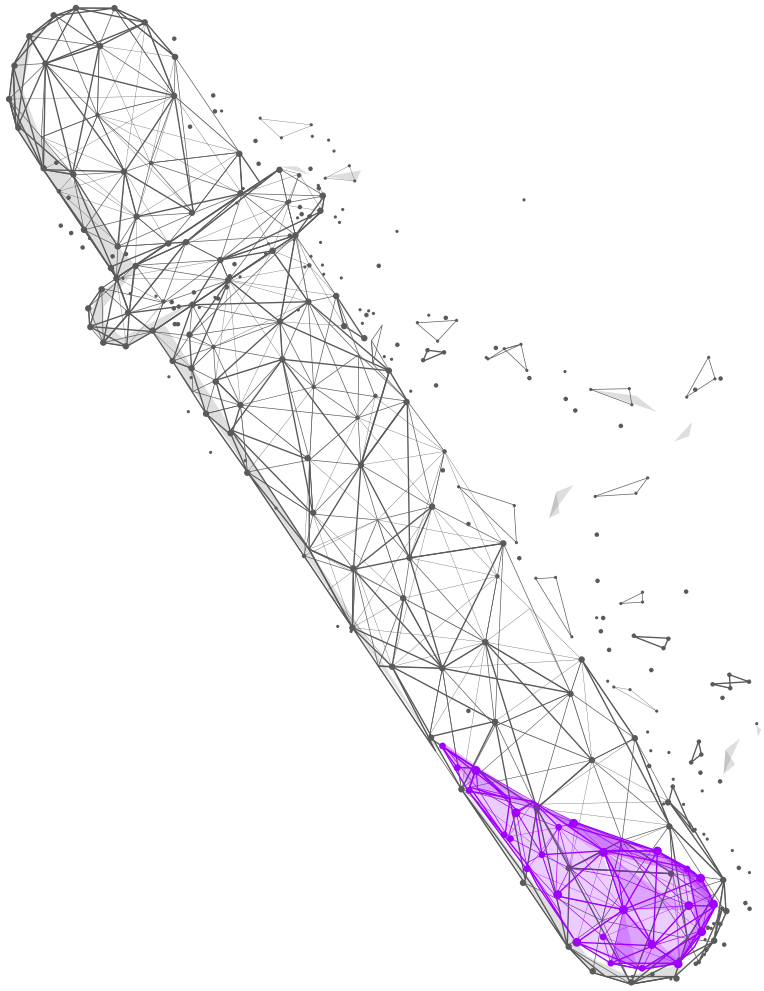
Analyzing business value against implementation feasibility of different capabilities and solutions supports definition of a strategic road-map to unleash the potential of Regulatory data, and equally the potential of the Regulatory workforce. This will ultimately help new products reach the marketplace faster and with greater precision than ever before, benefiting patients globally.

99% of life sciences executives expect more data exchange with partners.

Automation is needed to support the data interoperability revolution in healthcare, as science, technology and regulation all advance and converge to change how and where patients' health and wellness needs are met.

The Accenture Technology Vision survey found 99 percent of life sciences executives expect the volume of data exchanged with their ecosystem partners to increase over the next two years.

These higher levels of data exchange put more pressure on Regulatory organizations that want to adopt automation. No partnership is going to work well unless Regulatory first gets its own house in order. A good foundation is possible by following a few fundamentals.



Driving principles to successfully redefine Regulatory through Intelligent Automation

Accenture recommends that all automation projects are:

Business-outcome orientated: Solutions must be business-focused, rather than simply automating a task or a function. Successful automation programs often start with an overhaul and redesign of old processes, or invention of new ones.

Human-centered: While eliminating repetitive tasks, Intelligent Automation should put people at the center of its service organization, augmenting the workforce by applying machines so that people can focus on higher-value analysis, decision-making, and innovation.

Technology-rich: Intelligent Automation solutions will often leverage multiple technologies, including open-source ones, from a broad ecosystem. Intelligent Automation needs to be integrated into the broader architecture of data sources and applications.

No matter how thoughtfully designed, however, there are common management pitfalls that could derail automation implementation projects.

Here are a few traps to avoid:

1. **Software Engineering Principles Violated**
   Many automation initiatives are carried out in silos leading to multiple overlapping objectives, resulting in chaotic programs.

2. **Disconnect between IT and Business**
   Businesses that make ad hoc implementations of RPA without aligning to the overall IT strategy lead to post-implementation support challenges and fall outs.

3. **HR Management**
   Lack of communication on how the workforce will be re-purposed post automation implementation can lead to internal unrest and possible attrition.

4. **Change Control**
   Ineffectively managing the communication of the implementation and its impact without proper change control and management.

5. **Responsible Automation**
   One key consideration missed in most automation initiatives: what are the ethical and legal implications when tasks are automated? Who is accountable and responsible for outcomes?

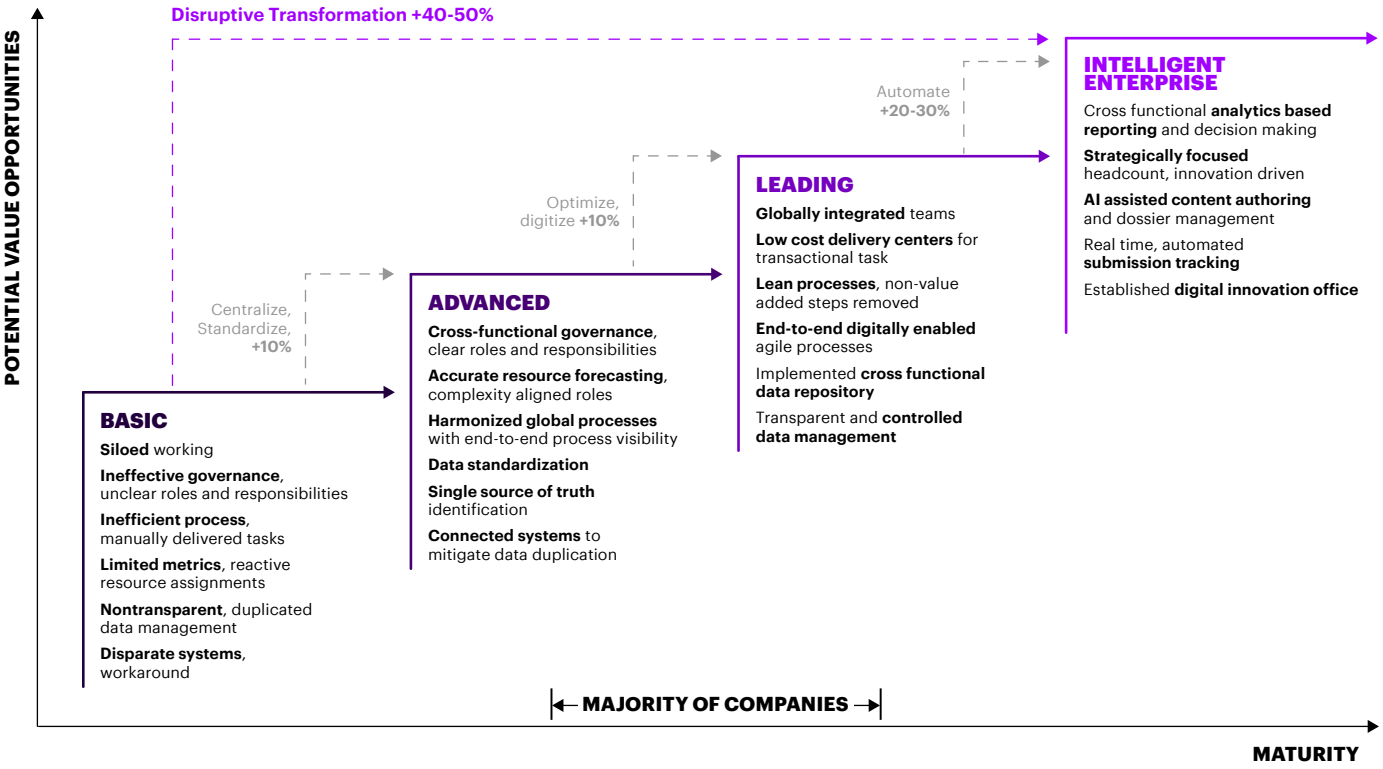
Accenture charts the journey to Intelligent Regulatory maturity

Becoming an Intelligent Regulatory function is not always smooth sailing.

Accenture has charted the typical journey a company takes to become an Intelligent Enterprise (see graphic below).

There are headwinds to face. Yet clients that mature from the basic stage to achieve Intelligent Enterprise status reap quantifiable gains. Based on Intelligent Automation projects that Accenture have delivered globally, it is estimated that companies that reach maturity can realize increased value ranging from 40 percent to 50 percent efficiency saving through a carefully managed disruptive transformation program.

Efficiency gains made by industries that have reached maturity prove this journey is worth the effort.



Accenture envisions large impacts

To sum up the Accenture vision, we recall a voice from the past.

Civilization advances by extending the number of important operations we can perform without thinking about them.

– Alfred North Whitehead, 1911

This concept still resonates.

Applying Intelligent Automation adds efficiencies and impacts on top of traditional improvement levers such as 'centralize', 'standardize' and 'optimize'. Accenture is helping life science companies to realize disruptive benefits that are above and beyond the tangible gains of cost, quality and productivity improvements.

With Intelligent Automation, Regulatory may experience:

- Seamless distribution of product information in a variety of multimedia channels to all internal and external stakeholders.
- Rapid and accelerating implementation of product advances that will propel continuous improvement.
- Advanced prediction of risks to mitigate against resource capacity constraints and product stock/wastage issues.
- Automation of up to 50 percent of currently performed manual maintenance tasks, resulting in significantly different future operating models where blended roles will prevail with strategic product oversight.
- Elimination of heavy reliance on in-country local Regulatory experts.
- Increased innovation in regulation/guidance updates as agility eliminates cumbersome roll out procedures.
- Improved staff satisfaction due to removal of routine tasks.

It's a brave new world in Regulatory Affairs.

The life science organization that matures into an Intelligent Enterprise will sail with confidence toward the horizon.

About Accenture

Accenture is a leading global professional services company, providing a broad range of services and solutions in strategy and consulting, interactive, technology and operations. Combining unmatched experience and specialized skills across more than 40 industries and all business functions—underpinned by the world's largest delivery network—Accenture works at the intersection of business and technology to help clients improve their performance and create sustainable value for their stakeholders. With 505,000 people serving clients in more than 120 countries, Accenture drives innovation to improve the way the world works and lives. Visit us at www.accenture.com.

Learn more

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