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The Future of Regulatory Affairs

FROM LUCID CONSULTING

LUCID CONSULTING 2023

THE FUTURE OF **REGULATORY AFFAIRS**

Lucid Consulting: A global consulting firm exclusively focused on the life sciences industry

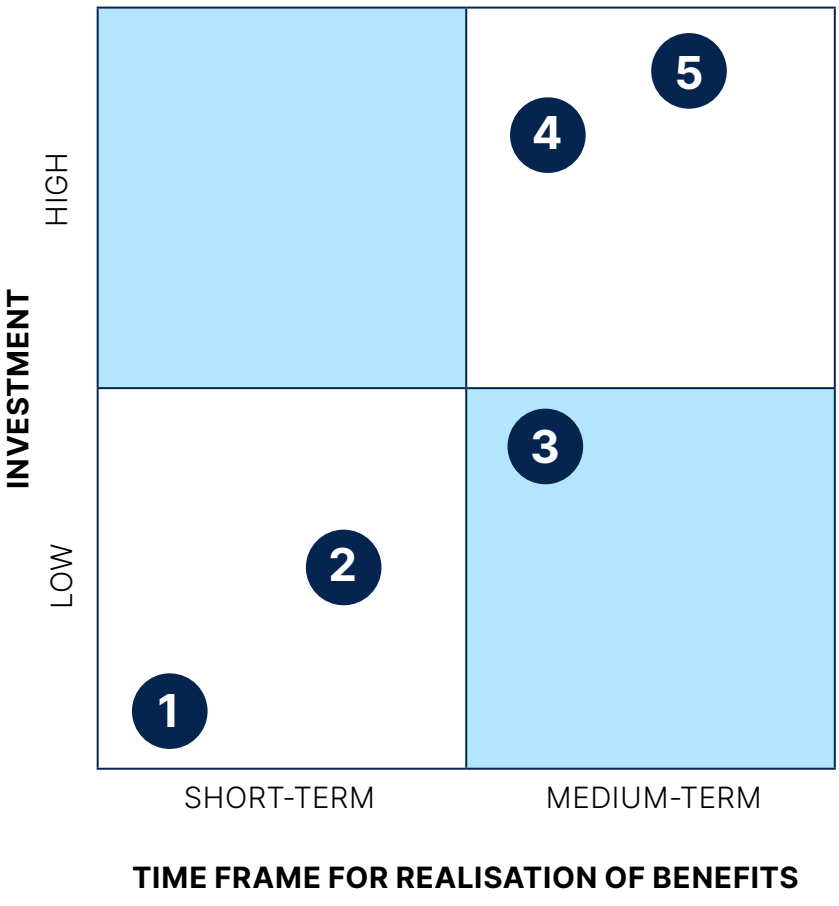
Deep health and life sciences expertise

The capabilities, discipline, and resources of a top-tier management consulting firm

Enhance **Regulatory Affairs'** contribution to the successful **development, commercialisation and lifecycle management of products** to **improve the lives of patients**

We see 5 priorities for Regulatory Affairs organisations to prepare for the future:

1. Enhancing the RA and PV interface
2. Optimising outsourcing
3. Preparing for new modalities
4. Driving efficiencies and quality through automation
5. Exploring machine learning and AI



1. ENHANCING THE RA AND PV INTERFACE

Effective working and management of information

Key interfaces where there is routine interaction between Regulatory Affairs and Pharmacovigilance functions:

1. Global Safety Committee
2. Global Labelling Committee
3. Medical and Regulatory Governance
4. Global Project Teams (GPT)
5. Periodic safety and pharmacovigilance reports for regulators
6. Post-marketing clinical trial approval studies
7. Country affiliate interactions
8. Audit and inspection

Large to mid-tier pharmaceutical company

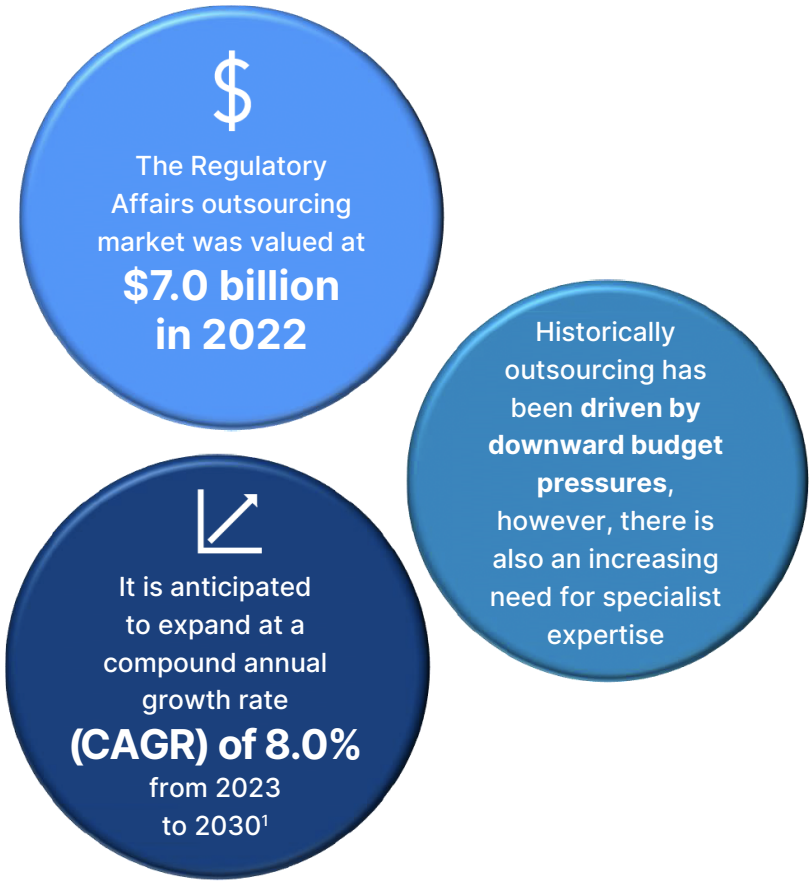
Specialised RA functional discipline

Specialised PV functional discipline

As these functions grow, **interfaces, communications and ways of working must** not only be maintained, but **continuously improved to optimise the management of information across and between the functions**

2. OPTIMISING OUTSOURCING

Realising value from outsourcing of Regulatory Affairs continues to be a challenge



Challenges and implications for outsourcing:
Higher than expected **oversight costs**
Poor performance management of the service provider
Inadequate appreciation of required **changes in work breakdown and workflows**
Resourcing challenges in the service provider
Lack of expected expertise
Transition costs, the **time** to embed a new provider and in the longer term the **loss of knowledge internally**
Legal and HR implications for FTE reduction which are complicated and sometimes costly in the short-term

3. PREPARING FOR NEW MODALITIES

Regulatory Affairs will need to adapt to support the evolving product landscape

- In the past 20 years there has been a **series of new innovations in science and technology**
- Regulatory Affairs within established biopharmaceutical companies are now expected to **support a much broader range of asset classes**

More recently, **digital health technologies are raising new challenges for regulatory authorities** as they prepare to introduce new pathways to enable these new technologies to be regulated

Large and mid-tier pharmaceutical companies with a legacy of small molecule development **must build or acquire capabilities to successfully prepare new modalities for product registration**

This may require **simultaneous authorisation applications to different regulatory bodies** within the same jurisdiction

Defining new competencies, adapting recruitment profiles, training of current staff and leveraging the expertise within acquired companies will help Regulatory Affairs adapt to their evolving product landscape

4. DRIVING EFFICIENCIES AND QUALITY THROUGH AUTOMATION

Digital transformation must meet the needs of stakeholders

Regulatory Landscape	Digital Transformation	Potential benefits
• As companies target global markets, **Regulatory Affairs (RA) interact with an increasing number of regulatory authorities**, making it difficult to establish common processes and submission documentation • Simultaneously, **regulatory authorities are collaborating** to increase their scrutiny of therapeutics	• As part of the digital transformation of R&D organisations, **RA are increasingly seeking opportunities to automate processes** to improve efficiency, compliance and accelerate time to market • These efforts should be considered alongside business processes, roles and vendor capabilities	• Enhancing efficiency by automating manual and repetitive processes and tasks • Improving knowledge management and collaboration between affiliates and HQ by automated sharing of country requirements • Facilitating advanced reporting and decision-making, improving transparency and compliance • Enhancing quality and compliance by improving document upload, quality control, and validation of RA systems • Facilitating real-time monitoring and timely responses to regulatory changes

RA organisations must ensure the transition to automated processes is designed in a safe and compliant way and that implementation aligns to the needs of regulators, data privacy and IT security.

5. EXPLORING MACHINE LEARNING AND ARTIFICIAL INTELLIGENCE

The use of machine learning and artificial intelligence within RA is in its infancy

- **Further innovation** in automation of RA is likely to be drawn **from advances in machine learning (ML) and artificial intelligence (AI)**. While the current application of this technology is limited to early adopters, pharmaceutical companies are exploring their use in the creation and translation of product labels driven by regulatory intelligence and NLP
- **AI supplements existing technology to improve productivity** e.g., with accurate search engine results, scheduling meetings, and content generation

Innovations come with challenges

1

How will regulators approach a therapeutic developed with an AI component?

Review the draft guidance provided by regulatory authorities, contributing to industry bodies, and advocating on behalf of industry.

2

How could ML/AI help either reduce costs or improve waste reduction in RA?

Build and expand on automation. AI will be trained on datasets and will analyse datasets faster, and with fewer errors, than humans can.

3

Will more risk-averse organisations be able to implement ML/AI?

Implementation of new technology could threaten individual expertise, and roles and responsibilities.

New systems will need to be validated and governed appropriately to meet stakeholder expectations of integrity, governance and security.

BALANCING FUTURE BUSINESS-NEEDS AND INNOVATION WILL IMPACT REGULATORY AFFAIRS PROFESSIONALS AT ALL LEVELS

Challenges

1. Ensuring effective **cross-functional collaboration**

2. Outsourcing while **minimising oversight costs, and effort,** in managing service providers

3. Building **new competencies and capabilities** to respond to new modalities

4. Maintaining **regulatory compliance** with the introduction of digital technologies

5. Effectively **managing change** as new technologies are introduced which compete and outperform tasks performed by humans

Solution

01 GROWTH MINDSET

Growth mindset

Big picture thinking, innovation, creativity, agility, thoughtful risk taking, digital literacy, complex reasoning, and problem-solving

02 TEAMWORK

Teamwork

Curiosity, connection and collaboration, knowledge transfer and adopting innovation, influence, and communication

03 PERSONAL DEVELOPMENT

Personal development

Life-long learning, intellectual curiosity, resilience and optimism, generative leadership, external engagement

LUCID CONSULTING HAS A UNIQUE VALUE PROPOSITION

Combination of deep domain expertise in our Consulting group, augmented by a network of Regulatory SMEs…

…with the capabilities, and discipline of a top-tier management consulting firm

Focus on the research, development and commercialisation continuum

R&D Operations	Clinical Development	Medical Affairs & HEOR	Regulatory	Safety & PV	Quality & Compliance

Insight, analysis & strategy development	
Assessment & benchmarking	
Operating model design & implementation	Process improvement, automation & digital enablement
	Organisational design, capabilities & performance management
	Sourcing strategies, vendor management & governance
Business cases & stakeholder management	
Transformational or incremental change program design & implementation	

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About Lucid Consulting

Lucid Consulting is the consulting division in Lucid Group focused solely on the life sciences industry. We bring a combination of deep health & life sciences expertise with the capabilities, discipline and resources of a leading management consulting firm. Our consulting teams have worked extensively in R&D and Medical Affairs. We continue to focus on emerging trends, needs and best practices across the industry.