White Paper

Empowering Mid-size Pharma Companies with Integrated Drug Development, Regulatory Strategy, and AI Innovation

MICHELLE GYZEN, Senior Director of Strategic Regulatory Solutions, IQVIA
BRIAN HEALEY, Global Head of Drug Development and Regulatory Strategy, IQVIA
CLAIRE DAVIES, Senior Director, Regulatory Affairs, IQVIA

Table of contents

Introduction

Mid-size pharma companies sit at a distinct intersection in the current pharmaceutical landscape. While their teams have the agility to innovate quickly, they may lack the scale, infrastructure, and resources of larger companies, creating both risk and opportunity. Without robust support, promising assets can stall, compliance gaps can emerge, and valuable market opportunities will fall by the wayside. However, with the right CRO partner, these organizations can convert high potential into speed-to-market.

Though many mid-size organizations may avoid the CRO route for fear of high costs, loss of control, or insufficient support, a strategic partnership can be activated to mitigate these concerns and transform potential challenges into advantages. A consultative, tech-enabled CRO can help small to mid-size pharma companies achieve their targets by supplementing their skillsets, expanding their global reach and infrastructure, magnifying their expertise, and designing an effective clinical, regulatory, and operational strategy.

A consultative, tech-enabled CRO can help small to mid-size pharma companies achieve their targets.

The consultative, end-to-end CRO model

Given the unique qualities of small to mid-size pharma companies, these organizations need an experienced and adaptable partner that offers end-to-end services, aligning clinical and regulatory functions with strategic technical innovation while saving money and increasing synergy. Global reach and flexibility are both imperative in a chosen partner.

So, what does an end-to-end model look like in practice? First and foremost, companies will have access to a team of experts to interact with across every stage of the product lifecycle. Drug development, clinical, bioanalytical, and regulatory solutions should collaborate seamlessly across functions to provide scientific, medical, and operational support. For mid-size companies without the existing infrastructure to accommodate every clinical development and lifecycle management component, CRO support is a major value add.

Each company has distinct needs. Because of this, it is critical to collaborate with a CRO that offers a flexible model in which services can be adapted to suit customer goals. A CRO with previous mid-size pharma experience will have services designed with these companies in mind. A consultative model should be informed by previous customer needs and designed to prioritize communication and change management alongside thoughtfully planned and controlled implementation.

If a company has limited resources, a CRO can provide strategic guidance on how best to execute a portfolio strategy based on the highest probability for success and ROI, helping a customer prioritize their resources accordingly. With end-to-end services, the CRO model doesn't just fill gaps for mid-size pharma, it levels the playing field by accelerating timelines, lowering development costs, and creating scalability as pipelines expand.

A robust regulatory approach

For companies looking to launch their first product successfully or expand their portfolio into new regions, real-time monitoring of regulatory standards is critical. At IQVIA, customers have access to the Regulatory Intelligence tool, a comprehensive database of historical regulatory information that helps mid-size pharma companies make informed decisions and design thoughtful development and regulatory strategies with high probabilities of success. AI is leveraged across this platform to provide simulated health authority responses, enabling customers to anticipate how regulators might respond to submissions.

IQVIA's experienced regulatory team includes former reviewers from the FDA, EMA, and other global regulatory authorities as well as team members strategically positioned around the world to provide guidance on local regulatory expectations. These experts are on hand to advise customers as they build a regulatory strategy aligned with their clinical and commercial goals. Using their deep experience and therapeutic, scientific, and regulatory expertise, team members provide customers with a level of regulatory insight that goes above and beyond, helping them to build clinical development plans and prepare for interactions with regulatory agencies.

This strategic support continues into the post-approval setting where lifecycle management and regulatory operations teams provide end-to-end support, allowing customers to transition seamlessly from clinical to commercial strategy. Bolstered by human expertise, emergent technology, and strategic insights, our lifecycle management services are comprehensive and equipped to accommodate adaptability in rapidly evolving regulatory landscapes. This highly skilled global team provides services to support different regions, health authorities, and language requirements while offering the flexibility to manage peaks and valleys in service demands. Our model is cost-effective and committed to continuous quality, compliance, and innovation.

IQVIA's lifecycle management services support:

- New pharmaceutical forms and dosages, which may entail changes to original licenses.
- Renewals to keep licenses active.
- Chemistry, manufacturing, and controls (CMC) variations.
- Labeling updates as pharmacovigilance knowledge grows.
- Administrative variations and changes to licenses.
- Tracking systems maintenance and administrative support.
- Withdrawals and deactivations due to safety or commercial decisions.
- Marketing authorization transfers (MATs) resulting from mergers and acquisitions.
- Project management.
- Regulatory intelligence and development of submission strategies.
- Authoring.
- Health authority interactions.

Our breadth of regulatory offerings empowers customers as they engage with global agencies across all stages of the product lifecycle.

IQVIA's experienced regulatory team includes former reviewers from the FDA, EMA, and other global regulatory authorities.

The strategic role of AI in mid-size pharma companies

For many mid-size pharma companies, AI may feel like a future-state aspiration: powerful but out of scope due to cost, complexity, or uncertainty about ROI. However, with strategic integration and development, AI is accessible and actionable rather than aspirational, offering mid-size organizations a competitive advantage.

Companies can leverage AI tools to directly support clinical and regulatory performance. From reducing submission timelines to enhancing document quality and process transparency, AI is reshaping workflows without massive infrastructure overhauls or specialized teams. With these efficiencies, mid-size companies can compete head-to-head with much larger organizations.

The IQVIA Regulatory Intelligence Assistant platform leverages machine learning and project-specific data to generate real-time reports and regulatory guidance queries, allowing teams to design smarter submission strategies, anticipate regulator concerns, and reduce costly rework. AI also supports the automated authoring of regulatory and clinical documents, shortening document development cycles by up to 66% while preserving quality and compliance. Along the way, domain experts are embedded at every stage to guide training review outputs and validate alignment with evolving regulatory standards. A rigorous commitment to data governance provides the foundation for scalable, resilient, compliant, and adaptable AI tools.

When thoughtfully deployed, AI is a pragmatic lever to increase speed, consistency, and confidence across the development lifecycle for mid-size companies. When implemented with the support of an experienced CRO, it becomes a force multiplier not just for efficiency, but for scalable growth.

AN IQVIA CUSTOMER SUCCESS STORY

IQVIA is currently in collaboration with a customer to develop their portfolio more extensively. The mid-size company has two assets in clinical development across five indications, with the potential for these assets to be developed in additional indications. Although the customer had the funding to expand clinical development activities for these assets into multiple indications, they lacked the human resources to do so. IQVIA supported this company's development activities by forming dedicated asset development teams for two additional indications. These asset teams were responsible for establishing the development program strategy and managing the asset through each development stage, from indication selection to marketing approval. This partnership allowed the customer to expand their development capabilities, remain at pace with organizations chasing similar targets, and keep their costs aligned with their growth strategy.

Secure your competitive advantage

Mid-size pharma companies do not need to operate at a disadvantage. In fact, a strategic CRO can unlock the infrastructure, technology, and global reach of large pharma companies while maintaining the agility that sets them apart. By opting to work with a partner that offers flexible support models, regulatory intelligence, and AI-driven efficiencies, mid-size pharma companies can position their therapies to lead in today's highly competitive market.

About the authors

MICHELLE GYZEN
Senior Director of Strategic Regulatory Solutions, IQVIA

Michelle has over 20 years of experience in the pharmaceutical, biotech and medical device industries. She is a senior director with expertise in designing large-scale regulatory outsourcing programs, offshore resource modeling and regulatory tech integration and automation. In her current role, Michelle is involved in designing strategic solutions for regulatory compliance, with a focus on operational efficiency, scalability, and technology.

BRIAN HEALEY
Global Head of Drug Development and Regulatory Strategy, IQVIA

As Global Head of Drug Development and Regulatory Strategy at IQVIA, Brian leads a global team of physicians, scientists, data analysts, and regulatory experts who provide innovative and customized solutions for pharmaceutical and biotech customers across the development lifecycle. Brian has over 23 years of pre-approval and post-approval pharmaceutical industry experience in clinical research, drug development, and regulatory affairs.

CLAIRE DAVIES
Senior Director, Regulatory Affairs, IQVIA

Claire is a highly experienced regulatory professional with over 20 years of CMC expertise. Claire's role includes managing projects for preparation of CMC variations, IMPDs and MAAs for small molecules and biologics in EU and international markets.

About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of clinical research services, commercial insights and healthcare intelligence to the life sciences and healthcare industries. IQVIA's portfolio of solutions are powered by IQVIA Connected Intelligence™ to deliver actionable insights and accelerate innovations. With approximately 88,000 employees in over 100 countries, IQVIA is dedicated to accelerating the development and commercialization of innovative medical treatments to help improve patient outcomes and population health worldwide. Learn more at www.iqvia.com.

CONTACT US

iqvia.com/globalcompliance