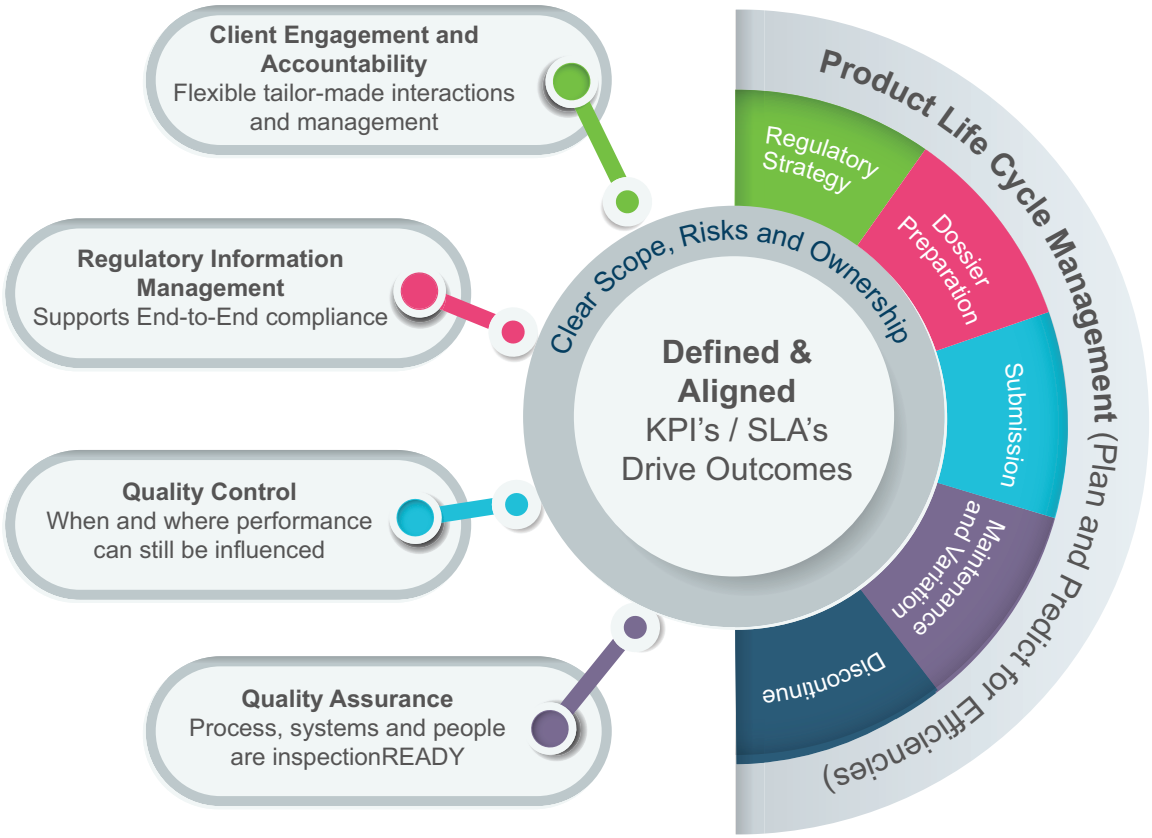
End-to-End Regulatory Services

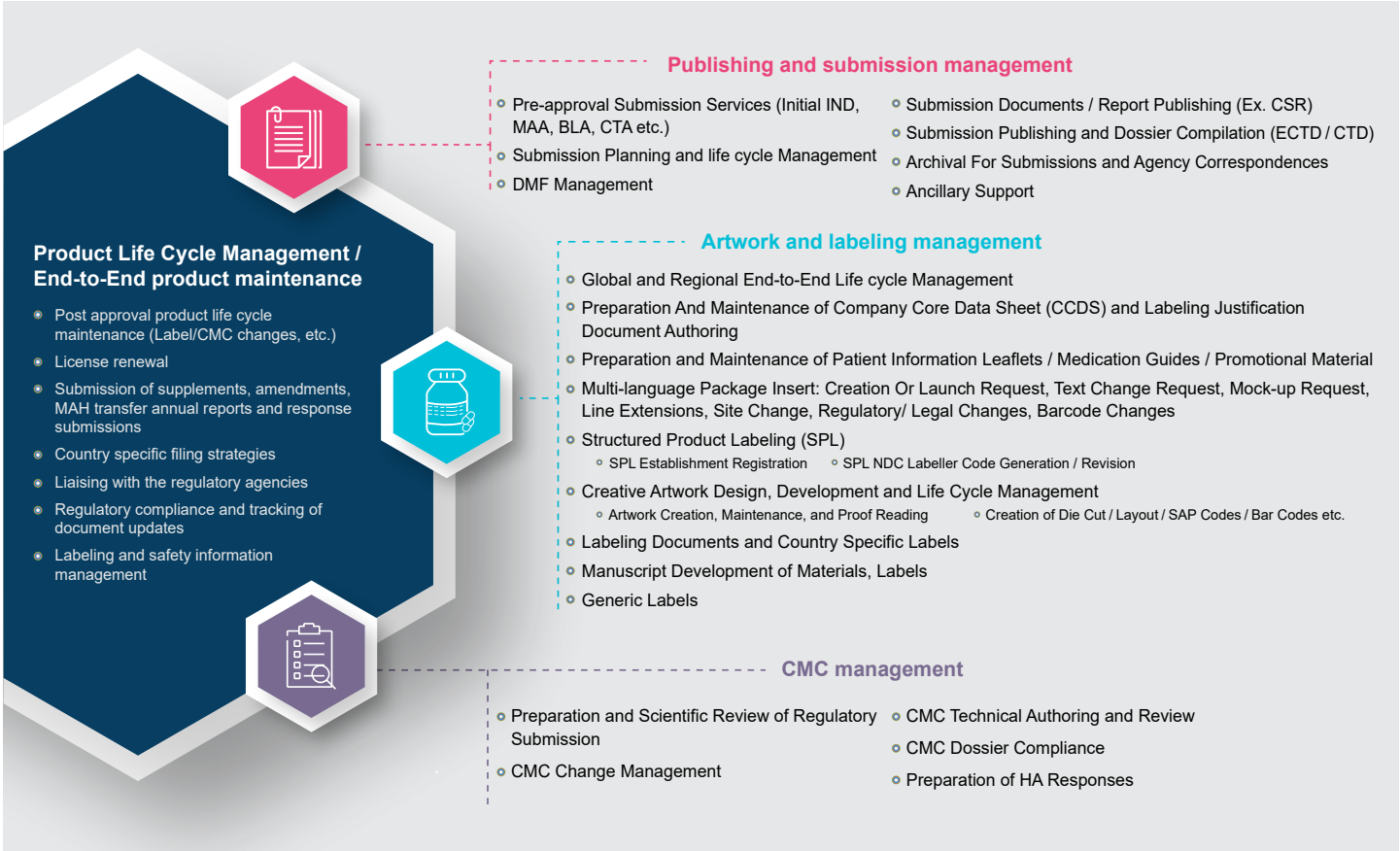
Life Sciences organizations constantly grapple with challenges pertaining to staying compliant with new regulations, gaining country-wise regulatory intelligence, implementing technology upgrades and automation, all while ensuring tight cost controls and savings. Regulatory Affairs works to ensure proactive compliance while driving operational efficiency to enhance business value. Navitas Life Sciences has conducted 50+ regulatory consulting engagements, has enabled over 170,000 global regulatory submissions, has developed 4 specialized IPs for regulatory affairs, and hosts 4 proprietary industry networking forums for regulatory professionals. We offer you the benefit of our extensive expertise and insights to drive outcomes for your regulatory affairs.

Strategic partnerships to drive First-Time-Right submissions and enable Product Life Cycle Management



Comprehensive Coverage of Regulatory Affairs

Navitas Life Sciences provides clients with end-to-end regulatory submission services. Our offerings span the entire gamut of regulatory affairs, right from publishing and submission management, to artwork and labeling management, to CMC management – we enable you to manage your product throughout its life cycle.



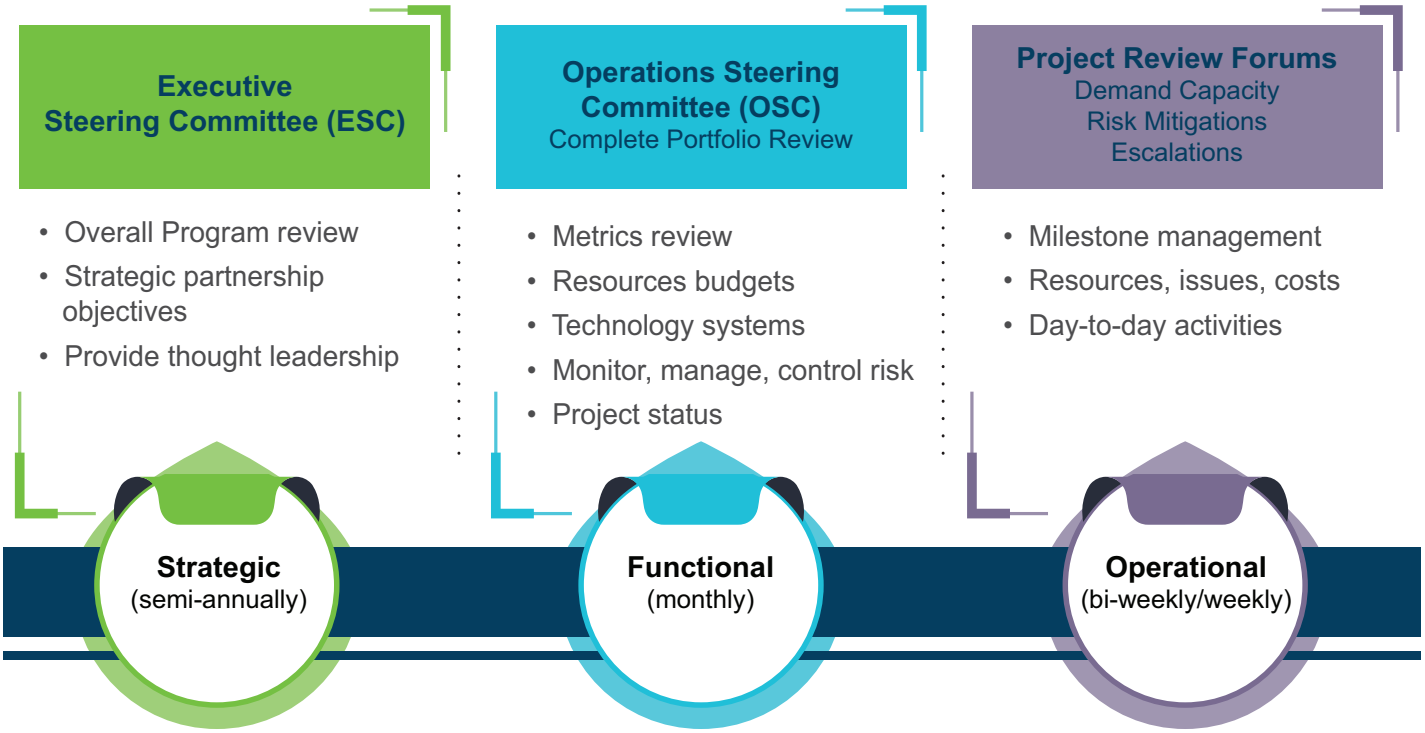
Complementary Delivery Organization

Navitas Life Sciences delivers outcomes through a model that reflects your organization and ensures that you have complete rein over the product life cycle and quality assurance. We act as an extension of your organization with a 24/7 project management operating model to support regulatory affairs. With multiple offices across the globe, the integrated and flexible approach drives down cost, and ensures timeliness and quality of submissions.

Collaborative framework to ensure quick issue resolution and seamless operations

Leveraging The Power of Collaboration		
Single Point of Contact (SPOC)	**Governance Model**	**Competitive Intelligence**
We offer a dedicated resource to manage and oversee operations, escalations, and clarifications of issues. Navitas Life Sciences supports day-to-day operations to align stakeholders toward goals. A SPOC is available for every client.	Navitas Life Sciences offers a governance framework to support interactions at all levels of the organization and support strategic decision making. This cuts across levels such as project and delivery teams to functional leadership and senior leadership. The model ensures a continual flow of value addition and novel approaches.	Thought leaders at Navitas Life Sciences tap market intelligence to drive innovation. Gain insights from our collaborative networks of industry leaders. Our networks community brings together industry peers to discuss trends, insights, and future solutions. Each network has a focused and evolving agenda, addressing key industry themes relating to Pharmacovigilance and Regulatory.

Robust governance to drive value for clients



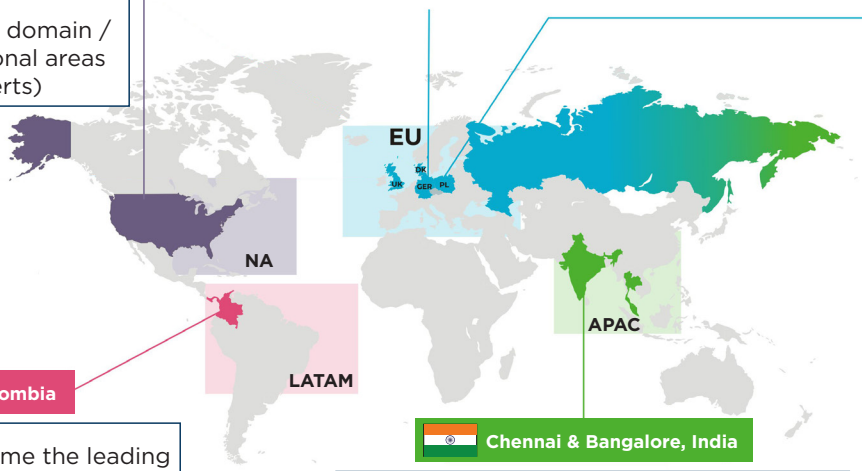
Competitive, tiered-pricing structure to meet your needs

MODEL	DEFINITION	BENEFITS
Volume Based Pricing	**A unit-based model for improving cost oversight** This model involves a fixed price for a certain volume of work	Eliminates financial risk if the resource requirements change
24/7 Based Pricing	**A model for enabling global delivery** A global 24/7 operating model that is independent of the location	Eliminates financial impact when regional work allocations change
Activity Based Pricing	**A fixed model for a portfolio of activities** A fixed pricing approach for a range of client activities	Guarantees efficiency without impacting the budget
Portfolio Based Pricing	**A fixed model for a mature portfolio** A combination of all the models to ensure seamless delivery. This model is apt for well-planned End-to-End submissions that involve low risk	A cost-effective pricing alternative for submissions that require minimum oversight, handoffs, and efforts
FTE Based Pricing	**A fixed & predictable model based on demand** A Full-Time Equivalent (FTE) model that enables clients to increase budget and resources by 10%	An apt pricing model for scaling up whenever required at no additional cost

Multiple Facilities Across the Globe

Princeton, NJ, United States

USA Corporate HQ with expanding capabilities in regional expertise and domain / operational leadership across functional areas (e.g. Biostatisticians, regulatory experts)



Bogotá, Colombia

Delivery center to become the leading operating centers for LATAM-clinical, regulatory and safety services

Chennai & Bangalore, India

Navitas Life Sciences Pvt. Ltd., Clinical / BA/BE studies, Regulatory, Safety operations and technology center

REASONS TO PARTNER WITH NAVITAS LIFE SCIENCES

- First-Time-Right Submissions Health Authority Liaison and Tracking Localized Regulatory Intelligence
- Global Delivery Capability Technology Integration Follow-the-Sun Model Support Proactive process improvement
- Strategic partnership model Cost Effective Operating Model Robust Governance & Transparency

Proven Expertise in Regulatory Affairs

- **95,000+** eCTD Submissions
- **20,000+** NeES Submissions
- **35,000+** Paper Submissions
- **100+** Regulatory Professionals
- **7+** Years of Average Experience
- **200+** Customers
- **5+** Technologies
- **100+** Health Authorities

NAVITAS LIFE SCIENCES

About Navitas Life Sciences

Navitas Life Sciences is a proven life sciences partner, enabling insight-driven decisions at every stage of the clinical development pipeline. Providing End-to-End Services and Solutions, we help address critical problems and drive outcomes. We bring together the capabilities of a full-service CRO with technology-led services across Regulatory, Safety, and Clinical with expertise in analytics and data sciences. With a rich legacy of experience and expertise, we offer Regulatory Strategy and Consulting, End-to-End Regulatory Services, Regulatory Technology for One Source of Truth, and our Industry Leading Regulatory Networks to help navigate the constantly evolving regulatory landscape and ensure patient safety. We have successfully delivered 200,000+Regulatory Submissions to 100+ global Health Authorities, for 200+ Life Sciences companies including: 132,000+ eCTD, 28,000+ NeES, and 40,000+Paper.

For more information

Americas +1 609 720 1002 **Europe** +44 (0) 2392 268133 **APAC** +91 44 4590 9000

contact@navitaslifesciences.com www.navitaslifesciences.com /company/navitas-life-sciences